ARESA
Advancing Research Ethics in Southern Africa
INTRODUCTION
In June 2011 the Centre for Medical Ethics and Law, Stellenbosch University and the Center for Bioethics, University of North Carolina were awarded a capacity development grant from the Fogarty International Centre of the National Institutes of Health (NIH) to develop and present the ARESA (Advancing Research Ethics training in Southern Africa) program. We offered a Postgraduate Diploma in Health Research Ethics (PGDip) and hosted an Annual Seminar in Research Ethics from 2012-2016. In total 40 mid-career professionals from the African continent have graduated with the Postgraduate Diploma in Health Research Ethics. All our trainees have conducted research (both empirical and conceptual) and have added significantly to the body of knowledge in research ethics in resource depleted contexts. We have hosted 5 ARESA Seminars attended by delegates from throughout the continent and in 2016 the Research Ethics Committee Association of Southern Africa (REASA) was launched. Many of our graduates have progressed to other degrees, to serve on Research Ethics Committees or to serve as consultants in Research Ethics. The program has been co-directed by Prof Keymanthri Moodley and Associate Professor Stuart Rennie over the past 5 years.
ARESA PROGRAM DIRECTOR

Prof Keymanthri Moodley
MBChB (Natal), M FamMed cum laude (Stell), M Phil cum laude (Applied Ethics) (Stell), FCFP (SA), DPhil (Stell) Executive MBA (UCT) is a Professor in the Department of Medicine and Director of the Centre for Medical Ethics and Law, Faculty of Health Sciences, Stellenbosch University. She is a family physician and a bioethicist. In 2013 she was rated by the National Research Foundation (NRF) as an established researcher based on her numerous national and international publications, conference presentations, her role on national bodies like the MRC Board and the National Health Research Ethics Council (NHREC) and her involvement in international organisations - the WHO, International AIDS Society (IAS) and NIH DSMBs. The Centre has been designated as a Collaborating Centre in Bioethics by the World Health Organisation, one of seven in the world and the first on the African continent. Since 2011, Keymanthri has co-hosted an NIH Fogarty program to develop capacity in Health Research Ethics in Africa in collaboration with the Bioethics Center, University of North Carolina-Chapel Hill, USA. The program has graduated 40 postgraduate scholars from 10 African countries over the past 4 years. In 2013 she was awarded a second NIH grant to examine the ethical and social issues associated with HIV Cure research. In 2015 the Centre was awarded its third NIH grant to explore ethical, legal and social issues related to genomic biobanking. Keymanthri is a member of the Academy of Science in South Africa and completed an Executive MBA in 2015. She is currently Chair of the MRC REC and has been appointed Adjunct Professor in the Department of Social Medicine, University of North-Carolina-Chapel Hill, USA.

ARESA PROGRAM CO-DIRECTOR

Prof Stuart Rennie
Stuart Rennie is Associate Professor in Social Medicine at the University of North Carolina at Chapel Hill and Core Faculty at the UNC Bioethics Center. He obtained a Masters in Anthropology and a PhD in philosophy from the University of Leuven, Belgium. Dr. Rennie’s current teaching and research interests focus on bioethics in developing countries, primarily in sub-Saharan Africa. He is co-Principal Investigator of a NIH/Fogarty International Center bioethics capacity building project in Central Francophone Africa, and co-Principal Investigator of a study on the ethical and social implications of HIV cure research. Dr. Rennie was Visiting Lecturer at the Center for Bioethics in Stellenbosch and Lecturer in Applied Ethics at the University of Cape Town. He has published on a variety of bioethics themes, including informed consent, HIV testing policies, implementation ethics, research involving children, health surveillance, and health inequality. He also writes for his own Global Bioethics Blog. He has been appointed as Extraordinary Associate Professor in the Centre for Medical Ethics & Law, Department of Medicine, Stellenbosch University, South Africa.
ARESA ADVISORY COMMITTEE 2012-2015

Prof Lesley Burgess
Professor Lesley Burgess MBChB, MMed, PG Dip (International Research Ethics), PhD, MSc Clinical Research) has been involved in clinical trials since 1992. She is the Managing Partner of TREAD Research, the only AAHRPP accredited research unit in Africa. To date, she has more than 95 publications to her credit, in addition to being the author of 3 chapters in internationally recognized textbooks for clinical research. She has given a number of talks both nationally and internationally on various aspects of clinical research, in particular patient recruitment and retention. She sits on the Stellenbosch University Health Research Ethics Committee and the Medical Research Council, and lectures for both the Pharmacology and Bioethics Departments at Stellenbosch University. She is currently a reviewer of the Clinical Trials Committee of the Medicines Control Council, as well as being a member of the GXPX (Compliance) Committee. She is also affiliated to the Wits Health Consortium – particularly with regards to training and quality assurance. She was appointed onto the executive committee for the accreditation of GCP courses in South Africa and also served on the executive committee of SACRA for 3 years. She has recently launched a new non-profit company called “Medical Legends” which is aimed at educating the general public about clinical trials, as well as enhancing patient centricity within clinical trials and developing tools to enhance participant understanding.

Prof Suzanne Maman
Suzanne Maman is a Professor of Health Behavior at the University of North Carolina Chapel Hill. Trained as a social scientist in public health, she has 20 years of research experience related to HIV/AIDS and gender-based violence in sub-Saharan Africa. Dr Maman’s work focuses on two aspects of the association between HIV and violence: 1) violence as a barrier to implementing HIV risk reduction strategies and; 2) violence as an outcome of HIV testing and HIV status disclosure to sexual partners. She has developed, implemented and evaluated interventions to address these associations in South Africa and Tanzania.

Neil Myburgh
After graduating from Wits he worked as a dentist in the Crossroads squatter camp. Later he completed specialist training in Community Dentistry at UWC, got involved in public health, research, policy formulation and ran a WHO Collaborating Centre. Based in the UWC Dept of Community Oral Health, he is responsible for courses in research method, epidemiology, health policy, ethics and human rights. He completed the Postgraduate Diploma in International Research Ethics at UCT with distinction in 2010 and presents monthly ethics workshops to all categories of health workers.
Prof Sudeshni Naidoo
Sudeshni Naidoo is Emeritus Professor at the University of the Western Cape. She is also the Director of the WHO Collaborating Centre for Oral Health. She is involved mainly with post-graduate education and training and her main focus of research is on Ethics, Bioethics and Research Ethics Infectious Diseases and Infection Control, and Oral Health Quality of Life, Trauma and Child Abuse. She has written Ethics, Research Ethics, HIV/AIDS and Hepatitis B vaccination policies, published and presented on Ethics, Child Abuse, Cross infection, Hepatitis and HIV/AIDS. She has successfully supervised and graduated over 50 Masters and 12 Doctoral students. Professor Naidoo has presented numerous scientific papers of her research findings at international conferences and has been an invited and keynote speaker, nationally and internationally on several occasions. She has been a member of the Medical and Dental Professional Board of the Health Professions Council of South Africa, Past President of the SA Division of the IADR and current President of the International Dental Ethics and Law Society.

ARESA CO-ORDINATOR

Dr Ciara Staunton

ARESA ADMINISTRATORS: 2012-2015

Mrs Meagan Leukes
Mrs Kelsey Engelbrecht
ARESA FACULTY MEMBERS 2012-2015

International Lecturers:

Prof Stuart Rennie – University of North-Carolina, USA
Amy Corneli – University of North-Carolina, USA
Dr Anne Lyerly - University of North Carolina, USA
Prof Eric Juengst - University of North Carolina, USA
Dr Susan Bull - Ethox Center, UK
Dr Ciara Staunton – Ireland
Prof Dan Nelson - University of North-Carolina, USA
Prof Arlene Davis - University of North-Carolina, USA
Dr Adam Gilbertson - University of North Carolina, USA

National Lecturers:

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<th>Miss Kathy Lawrence</th>
<th>Prof Gboyega Ogunbanjo</th>
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<td>University of Limpopo</td>
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<td>Prof Landon Myer</td>
<td>Mary Lister</td>
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<td>Prof Lesley Burgess</td>
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<td>Prof Soraya Seedat</td>
<td>Prof Anne Pope</td>
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<td>Prof David Hall</td>
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<td>Prof Theresa Rossouw</td>
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<td>Prof Haylene Nell</td>
<td>Prof Dirk Louw</td>
<td>Dr Malcolm de Roubaix</td>
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ARESA FACULTY 2012-2015

Prof Eric Juengst          Dr Amy Corneli             Katherine Lawrence     Prof Marc Blockman    Dr Terry Fleischer

Prof Jerome Singh       Prof Landon Myer        Prof Lesley Henley       Prof Leslie London

Prof Gboyega Ogunbanjo    Prof Jerome Singh     Prof Landon Myer        Prof Lesley Henley     Prof Leslie London

Dr Haylene Nell           Prof Willie Pienaar    Prof Anton Van Niekerk    Prof Sharon Kling     Dr Malcolm de Roubaix
WHERE ARE OUR ARESA GRADUATES NOW?
Postgraduate Diploma in Health Research Ethics: Graduates 2012

Prof Blanche Pretorius
BA, BA Hons (Social work), MA (Clinical Social Work), D Phil Social Work.
I graduated with the degree Bachelor of Social Science (Social Work) from the former University of Natal, Durban. I later pursued Honours, Master’s (Clinical Social Work) and Doctoral studies at the former University of Port Elizabeth (now NMMU). My current involvement in the area of research ethics is on a number of levels: as chairperson of the NMMU’s Research Ethics Committee (Human) since 2008, as RCD responsible for the administrative oversight of research ethics at NMMU and research supervision of doctoral candidates in Social Work and Nursing Science. I currently hold the position of Director in the Department of Research Capacity Development at the Nelson Mandela Metropolitan University (NMMU).

Adv Jamwell Maswanganyi
I have served on the Research Ethics Committee (TUT) and the Steve Biko Academic Hospital Management Board until recently. I completed an MPhil in Applied Ethics. I have just commenced my LLD studies with UNISA, focusing on an area dealing with health research ethics.

Prof Pramanathan Govender
BSc, BSc (Hons), MSc, PhD (Entomology)
Since graduating with the PG Dip (Health Research Ethics) I am Director of Research & Postgraduate Studies at the Sefako Makgatho Health Sciences University (SMU) in Ga-rankuwa, South Africa. I have been involved in undergraduate and postgraduate teaching and international research initiatives, with interests in Applied Entomology and the development of Integrated Pest and Diseases Management Programmes. I am currently the Acting Deputy Vice Chancellor of Research, Postgraduate Studies and Innovation and have been tasked with providing strategic management and leadership of cutting edge research and associated activities at SMU since the establishment of this new university in 2015. Since my graduation from the ARESA programme, I remain a core and active member (Animal Ethicist) of the SMU Research Ethics Committee (MREC) and the Research Directorate administratively manages the now level two accredited Ethics Committee.
Dr Beyene Ademe
MD, MSc (Medical Microbiology), Pg Dip (Medical Microbiology)
The Ethiopian NREC had no national research ethics guideline. During the last 3 years there were national forums and meetings to develop one. My contribution for the development of the document was important. As research and graduate coordinator we solved various problems. I am offering a Research Ethics Course with better confidence. Colleagues frequently consult me about what is expected for sound ethical procedure before commencing data collection and I became a resource person after ARESA the graduation. I have also submitted my ARESA Graduation thesis for publication.

Ms Margaret Ellis
BCur, BCur (Hons), MCur
I work as an SMO manager and SSC at Scion Clinical Research, an organisation that is involved in phase 1-4 clinical trials. I have a background in Nursing Science. I have a specific interest in the guidance and standards for GCP in South Africa, as well as in the design, conduct, recording and reporting of clinical trials.

Ms Adri Labuschagne
Bsc, BSc Hons, MSc
I am the Ethics Officer at the Medical Research Council in Cape Town. I have been involved with the administration of the MRC Ethics Committee since 1994. My functions include all aspects from compiling the agenda to logistics. I received a Certificate of Competence from the Wits Faculty of Health Sciences in Research Ethics: Conducting Research Responsibly. In 2015 I attended the 4th World Conference on Research Integrity where I presented a poster based on my research assignment. Currently I assist the Chair of the MRC REC in providing training to the committee members.

Thabo Molebatsi
BA Hons, MPH.
After completing the PG Dip (Health Research Ethics) I joined the Pharma-Ethics REC as a member in January 2016. I also participated in the review process and publishing of the 2015 SA Health Research Ethics Guidelines of the Department of Health. I served on the secretariat of the National Health Research Ethics Council of South Africa. I am currently working at Statistics South Africa.
Dr Ronell Leech
B Cur, BA (Nursing), BA Hons, MA, D Phil.
Since I graduated in 2013, I continued to serve on the Research Ethics Committee of the Faculty of Health Sciences, University of Pretoria. I presented several modules and oral presentations since then: Module on ethics in health research for interdisciplinary groups of students in the School of Healthcare Sciences, Faculty of Health Sciences, University of Pretoria. I was the Key note speaker talking about health research ethics at an annual research day of a College of Nursing in Gauteng Province. I lecture on health research ethics for interdisciplinary postgraduate students doing a proposal development course in the School of Healthcare Sciences, Faculty of Health Sciences, University of Pretoria. I lecture on research ethics for undergraduate students in the Department of Nursing Science, School of Healthcare Sciences. I presented on ethics in the neonatal intensive environment at a workshop presented by the Neonatal Nurse Association of Southern Africa. I am also busy compiling a manuscript on the presentation.

Dr Tina Malan
MBChB, Diploma in Mental Health
The most important achievement for me was that my ARESA research article: “Phase 3 Oncology trials in South Africa: Experimentation or Therapeutic Misperception?” was published about one year ago in the Journal of Empirical Research on Human Research Ethics (JERHRE). Otherwise I’ve just been very busy with the Psychiatry Training program, where I use the ethical and research ethics principles taught on the ARESA course on a frequent basis. My MMed thesis explores the “Incidental Neuroimaging Findings in Research Participants”.

Sabina Mubanga Luputa
Bachelors of Business Administration, MSc Project Management.
Since I graduated I have co published an article titled, “Academics and Integrity in Biomedical Research in Zambia: Personal and Institutional Responsibilities” in the Journal of Agricultural and Biomedical Sciences. I have also built capacity in the office of ERES Converge IRB which has become a source of information for researchers and students. I am currently the Director of Administrative Management. I have held two GCP Training Workshops for Community Representatives under the LAM Study, University Teaching Hospital. Under an EDCTP grant I have also participated in two Research Ethics sensitisation programs for people living in rural areas in Chongwe, Lusaka Province. I have contributed to the development of draft Regulations for Material Transfer and Bio Banking, under the National Health Research Authority. Since 2011 I have served on the ERES Review Board and since then I have been reviewing Protocols and offering advice on Research Ethics to post graduate students in Universities.
Jane Nabbuto  
Bachelor of Bio-Medical Laboratory Technology.  
Since completing the ARESA programme in 2012, I enrolled for a HIV/AIDS fellowship under the continuous quality improvement track with the Makerere University College of Health Sciences School of Public Health. Uganda National Council for Science and Technology had a problem with delays in providing feedback to research sites after field inspection. This led to a delay in responding to concerns provided by the auditors leading to violation or deviation from the approved protocols by the investigators. The rights of research participants were impacted. As part of the fellowship program, I designed and implemented a project to improve turnaround time for providing feedback to research sites after field inspections conducted by UNCST. I analyzed the root causes of the problem and put measures in place which helped to improve turnaround time from 3 weeks to 4 days. I am currently the head of training for the National HIV/AIDS Reference Laboratory at Uganda Virus Research Institute.

Dr. Geremew T Tsegaye  
MBChB, MA in Public Health.  
I am one the first ARESA graduates in 2012. Since then, I was selected to Chair our IRB, developed a SOP for our IRB on biobanking and long term storage of samples, revised our IRB SOP and developed and provided training packages on ethics, professionalism and medicolegal issues to Ethiopian Physicians and Researchers. I have provided research ethics training to different IRBs in Ethiopia and participated in the national effort of Creating Compassionate, Respectful & Caring health professionals by designing strategies, developing guidelines and training manuals.
**Prof Ashley Ross**  
Since graduation in 2013, I have moved up the academic ladder by appointment as Deputy Dean of Faculty in May 2014 and my recent appointment as Acting Executive Dean of the Faculty of Health Sciences at DUT since January 2017. On the Ethics front, I have participated as a member of the UKZN Biomedical Research Ethics Committee. I am currently engaged in developing materials for institutional Ethics training at DUT, and am Chair of the Faculty of Health Sciences Research and Higher Degrees Committee. I have participated on a number of NRF Health Sciences review panels, in which my active engagement in research and prior training in Health Research Ethics have been fruitfully applied. In 2015-2016, I was invited to participate in the HELTASA Teaching Advancement in Universities (TAU) Fellowship programme, and was awarded a TAU Fellowship in August 2016.

**Dr Christine Wasunna**  
BSc in Biochemistry, DPhil in Biochemistry.  
In April 2015, I joined the University of Massachusetts Medical School's Ebola Relief Effort in Liberia. I led the molecular diagnostics team and supported the Ministry of Health’s Men’s Health Screening Program for Ebola which was first to report the extended duration that Ebola Virus RNA can be detected in the semen of Ebola Virus Disease survivors. During my stay in Liberia, I trained the Ebola Virus Research Clinical Research Team (PREVAIL) on research ethics and Good Clinical Practice ensuring that the research staff completed NIH’s Protecting Human Research Participants and Good Clinical Practice Online Courses. I worked with the Administrator of the National Ethics Review Board to revise and strengthen the guidelines for conducting clinical trials in Liberia and also developed forms for submission and review of clinical trials. WHO's 2016 Guidance For Managing Ethical Issues In Infectious Disease Outbreak has been adopted by the NREB. In June 2016, I was appointed to serve on the H3Africa’s Data and Biospecimen Access Committee (DBAC) for a period of three years. I am a contributing author in the book “Research Ethics in Africa: A Resource for Research Ethics Committee; Edited by Mariana Kruger, Paul Ndebele, Lyn Horn SUN Press, June 2014”.

**Dr Tusubira Evans**  
BDS Maxillo-facial and Oral and Dental Surgery, MSc Vaccinology, Molecular Biology, Biotechnology Parasitology Proteomics.  
From the scorching poverty in the countryside to the thrilling dangers associated with cancer research, I have no option but to become a morally complex character piece drenched in the trappings of the research needs, healthcare needs and research ethics in order to navigate the very thin lines. I’m a member of the IRB of the Fred Hutchinson Cancer Research Center/Cancer institute, Mulago Hospital Kampala Uganda. In this setting, 90% of cancer treatment is provided under research. It is fatal for a patient not to participate in research but dangerous to participate in research. Which risk is better and who is morally obliged to determine it; the IRB or the patient?
Mrs Tanya Coetzee
BA Political Sciences, BA (Hons) Development Studies.
I am enrolled for the M Phil (Bioethics) at the University of Stellenbosch and am currently completing the mini-thesis. I am part of the Ethics Capacity Training Course presented by TUT/UNISA to Ethics Educators and am passionate about ethics education and the importance of teaching ethics to undergraduate students. I serve as member of the Faculty of Science Ethics Committee at TUT. Currently I am also on a Steering Committee and Secretary of the Research Ethics Association of Southern Africa (REASA).

Dr Alwyn Mwinga
BSc, BSc Human Biology, MSc Clin Top Med, MMed Internal Medicine.
Attending the ARESA program as a trainee has enabled me to obtain experiences and make connections that would not otherwise have been available, detailed below. I published, together with Prof Moodley, a paper based on my dissertation in BMC Med Ethics in 2014. I presented a poster at the 12th World Congress of Bioethics in Mexico City in February 2014. I have been appointed to the Board of the Drugs for Neglected Disease Initiative (DNDi) as a patient representative, a position that required experience of biomedical research, and ethics. This position led to my being nominated to attend a consultation organized by the Seton Hall Law School for a project entitled ‘Ethical Issues in Marketing Pharmaceuticals in Emerging Health Systems’ in Newark New Jersey in 2016. In addition I have been appointed to the Ethics Advisory Group of the Union (formerly Union against Tuberculosis and Lung Diseases).

Dr Liya Wassie Dubale
BSc (Applied Biology), MSc (Biomedical Sciences), PhD (Health Sciences/Immunology).
Currently, I am the Team Leader of Coordinators facilitating the Bioethics Course run by Partnership for Health Research Training in Kenya (PHERT) through a grant awarded by National Institutes of Health to University of Nairobi to develop and implement a research capacity program to support junior faculty. I am a Member of the National Bioethics Committee, Kenya and I have participated in writing a Research Ethics Manual in collaboration with Kenya AIDS Vaccine Initiative-Institute of Clinical Research and National Commission of Science, Technology and Innovation. The manuscript is awaiting finalization and publication. In 2016, I was involved in developing Standard Operating Procedures for Kenyatta National Hospital-University of Nairobi Ethics Research Committee and I participated in a Conference funded by the European Union on Creating and Enhancing Trustworthy, Responsible and Equitable Partnerships in International Research organized by TRUST and Partners for Health and Development in Africa.
Dr Nanette Briers
BSc (Physiology, Zoology), BSc Hons (Physiology), MSc (Physiology), DHETP Education, PhD Anatomy.
Since graduation, I accepted a senior lectureship at the School of Anatomical Sciences, WITS Medical School. I joined the Human Variation and Identification Unit (HVIRU) and obtained a NRF competitive grant for unrated researchers for further research in the field of forensic anthropology relating to human identification. I recently published the work I completed during the ARESA programme entitled “Ethical Issues Surrounding the Use of Modern Human Remains for Research in South Africa” in the Journal of Empirical Research on Human Research Ethics.

Dr Tyson Welzel
MBChB, Diploma in Primary Emergency Care, Higher Diploma in Internal Medicine, Diploma in HIV Management, Diploma in Tropical Medicine and Health, Diploma in Forensic Medicine, BSc (Med) Hons, European Master in Disaster Medicine, MScMedSc Clinical Epidemiology.
In April 2016 I joined Mediclinic International, PLC as the Group Manager in Clinical Standards. In this new position I am attempting to put systems in place to implement and standardise an electronic health record in the three operational platforms (Southern Africa, Switzerland and UAE), as well as provide evidence-based healthcare technology assessments for major investments, as well as provide framework pathways. I have also joined the Medical Advisory Committee for Remedi medical scheme. I am currently busy with my EMBA through the University of Cape Town.

Prof Joyce Tsoka-Gwegweni
BSc. Hons Biological Sciences, MSc Medical Parasitology, PG Certificate Geographic Information Systems, MPH, PhD Public Health, BA Hons Psychology.
After completing the ARESA program I was appointed as Head of the Biomedical Research Ethics Committee at the University of KwaZulu-Natal in Durban, for the period of March 2015 until March 2018. I also present lectures on Health Research Ethics to the third year medical students conducting community research projects for the Research Methods Module, at the Nelson R Mandela School of Medicine. In addition, I teach Health Research Ethics lectures to postgraduate students in the following programmes at the School of Nursing and Public Health: Research masters students registered for the degree of Master of Medical Science in Public Health. 2nd year Master of Public Health students doing the Research Methods and Bioethics Module and PhD students in the PhD Supervision Cohort Training Programme. I also serve as a member of the University Research Strategy Group (RSG) and the Institutional Biosafety Committee (IBC).
Dr Patrick Kamalo  
Bachelor of Medicine and Bachelor of Surgery, MMED Neurosurgery.  
In 2013 I was fortunate to be offered a Fogarty fellowship to study Postgraduate research ethics at the University of Stellenbosch. At the time I was serving as a member of the College of Medicine Research and Ethics Committee. My training in ethics helped me appreciate important ethical issues in the conduct of research. I particularly became interested in the subject of compensation for research injuries, in which I did my research assignment. So far I have published one conceptual paper in the Journal of Medical Ethics. I am currently drafting a manuscript from my empirical work and I have already presented part of this work at a major international EDCTP conference. I am no longer on the research ethics committee but with my skills in research ethics I act as a resource person for my peers, undergraduate and postgraduate students, during their student research activities. I also teach surgical ethics to final year medical students and act as a resource person for clinical ethics problems within our hospital. In November 2016 I received a travel grant to attend the 2016 Advancing Ethical Research Conference in California.

Mrs Tumulano Sekoto  
Diploma in Family Nurse Practice, BA (Health Services & Social Services), BA (Hons) Psychology.  
Since I graduated from the ARESA program, I have completed the Ethics Handbook for Botswana Harvard AIDS Institute Partnership due for launch this year. I am currently pursuing an MPH through UNISA, focus area Ethics. My abstract was accepted for a poster presentation at the Canadian Conference on Global Health, Montreal 2015: “Recruitment of participants into medical research in Botswana: Knowledge, attitudes and practices of research ethics by recruitment officers” and at the Durban IAS in 2016: “Demonstrating regulatory compliance of a novel electronic data management system in large scale community-based HIV prevention trial in Botswana”. I have been appointed by BHP to co-ordinate and oversee grant applications for the EDCTP Grant on Ethics and Regulatory Capacity building in January 2016.
**Postgraduate Diploma in Health Research Ethics: Graduates 2014**

**Prof Brenda Morrow**  
BSc, MSc in Physiotherapy, PhD in Paediatrics.  
In 2014 I completed the Postgraduate Diploma in Health Research Ethics through the ARESA program (cum laude). I am an academic in the Department of Paediatrics, University of Cape Town, where I engage in multi- and trans-disciplinary research, undergraduate and postgraduate teaching and supervision across many disciplines. To date I have over 70 peer reviewed publications (three of which are Bioethics papers published after ARESA qualification); have co-edited a textbook on Cardiopulmonary Physiotherapy in Trauma (the first in its field); written 11 book chapters; and presented at numerous national and international medical congresses. I chair the Departmental Research Committee; and am a member of the Faculty of Health Sciences Human Research Ethics Committee (for the second term), and the Steering Committee of REASA. I am a regular reviewer for numerous international journals. I was promoted ad hominem to full Professor in 2017.

**Mr George Rugare Chingarande**  
DCR Radiotherapy & Oncology, BTech Nuclear Medicine & Radiotherapy, MBA – Healthcare Management.  
Since graduating I have been a Fulbright Scholar at the University of Missouri, Columbia. I have been working on research focusing on the production and functionalization of radioactive nanoparticles for cancer diagnosis and treatment. I am currently working on my PhD thesis. I have also completed a postgraduate certificate in Nuclear Safeguards Science and Technology.

**Dr Fanuel Lampiao**  
BEd, BSc Honours, MScMedSci, PhD.  
I am an Associate Professor of Physiology at the College of Medicine in the University of Malawi. I was in the 2014 ARESA Postgraduate Diploma in Health Research Ethics cohort. I graduated in March 2015. Before I enrolled into the program, I used to serve as a member of our institutional research board (IRB) and the Dean of Students. After graduating I have been involved in several projects that required my expertise in research ethics. For instance, I was co-opted to be a lead in research activities in the NORHED funded project where I assisted MSc and PhD students during their proposal development on ethical issues. I am also a member of the Centre for Bioethics in Eastern and Southern Africa. The centre is involved in teaching and conducting trainings in bioethics. Recently I was appointed to become the Dean of Postgraduate Studies and Research. In this position the IRB is under my jurisdiction. The administrator of the IRB reports to my office.
Dr Farayi Moyana
Bachelor of Dental Surgery/Science, MBA, MPH, PG Dip in Dentistry.
I graduated from the Postgraduate Diploma in Health Research Ethics (ARESA) in the 2014. In 2015 I was accepted on the MPhil (Applied Ethics) Masters programme at Stellenbosch University. I am currently completing my dissertation entitled: A System in Crisis: Ethical Concerns about Zimbabwean Healthcare in the 21st Century. I was appointed as a Dental Advisor for a leading Medical Aid Society in Zimbabwe in 2015.

Dr Sunita Potgieter
BSc Dietetics, Master of Nutrition, PhD (Nutritional Sciences).
Since graduating from the ARESA course in December 2014, I have had my twins (who I was expecting during the ARESA PG diploma), I continued to work as Vice-Chair of the Health Research Ethics Committee during 2015 and then resigned as Faculty member at the University of Stellenbosch to fulfill my lifelong dream of studying Medicine. I am now a second-year MB ChB student at Stellenbosch University and I am enjoying every minute. In terms of Health Research Ethics–I am not a full member of the HREC committee any more, but still review progress reports and research proposals on an ad-hoc basis for the committee.

Dr Anna-Marie Wium
B (Log), M.Comm Pathology, D.Phil Comm Pathology, PG Dip (Higher Education).
In December 2015 I graduated with a Post Graduate Diploma in Health Research Ethics at University of Stellenbosch. Currently I am a member of the Sefako Makgatho Health Sciences University REC. I was one of a small group who have developed a short course for faculty development. Programme evaluation was done as independent research. My article was submitted for review in August 2016. I am a founding member of a ‘Community of Practice’ at SMU. In September 2016 I obtained a Teaching Development Grant from DoHET. I Invited Prof Rhea Paul from Sacred Heart University to build capacity among staff at SMU. Presentations:

- An ethical perspective on ototoxicity management. Ototoxicity symposium. Sefako Makgatho Health Sciences University.
Dr Lillian Otieno-Omutoko
Diploma in Education, Bachelor of Education, Master of Arts Degree in Education, PhD in Education. Currently, I am reviewing the curriculum for Ethical Issues in Research for a Postgraduate Diploma in Research Methodology. I am the Team Leader of Facilitators of the Bioethics Course run by Partnership for Health Research Training in Kenya (PHERT). This is through a grant awarded by National Institutes of Health to University of Nairobi to develop and implement a research capacity program. Since 2015, I have served as a Committee Member of National Bioethics Committee, Kenya. Additionally, I have participated in writing a Research Ethics Manual. This was in collaboration with Kenya AIDS Vaccine Initiative, Institute of Clinical Research and National Commission of Science Technology and Innovation. In 2016, I was involved in developing Standard Operating Procedures for Kenyatta National Hospital-University of Nairobi Ethics Research Committee. I also participated in a conference on Creating and Enhancing Trustworthy, Responsible and Equitable Partnerships in International Research organized by TRUST and Partners for Health and Development in Africa.

Prof Minrie Greeff
BA (Nursing Science), Masters (Nursing Science), PhD (Nursing Science). Since completing my training in December 2014, I have changed positions at the North-West University. In January 2015, I became Head of the Faculty of Health Sciences Ethics Office for Research, Training and Consultation but I still conduct my research in the Africa Unit for Transdisciplinary Health Research. Since no office existed, I had to build the office from scratch to support both human and animal research ethics committees. This was an interesting and challenging journey to facilitate change at such a large scale. The office has grown and has four support staff and one academic advisor to support this endeavor. During 2016 I have also trained all other research ethics committees within other faculties and am at present facilitating the registration of another REC on campus to serve five other faculties, not involved with health or health-related research. At the end of 2016, I was appointed as member of the National Health Research Ethics Council for a term of three years.
Prof Walter Jaoko
Bachelor of Medicine & Bachelor of Surgery, Masters of Tropical Medicine, Diploma Research Methodology, PhD in Medical Microbiology.
Since graduating from the ARESA program, I have been deeply engaged at the Kenya Pharmacy and Poisons Board, the national drug regulatory authority, in its Expert Committee on Clinical Trials as the Vice-Chair. PPB is mandated by the Kenya Government to review all clinical trials on candidate drugs, vaccines and devices in the country. Although a prerequisite for submission of study protocols for review by PPB is that they must have obtained ethical approval, PPB review includes both scientific and ethical review and in this regard I have found the ARESA training very useful. I have also continued to assist masters and PhD students at the University of Nairobi in reviewing their research proposals for both science and ethics prior to their submission to their respective departments and Kenyatta National Hospital Ethics and Research Committee for scientific and ethical approval. Finally, I have published the work from my Postgraduate Diploma in Health Research Ethics. Jaoko W, Bukusi E & Davis AM (2016) entitled “An evaluation of the Middle East Research Training Initiative (MERETI) tool in assessing effective functioning of research ethics committees: Experience with a Kenyan REC” in the Journal of Empirical Research in Human Research Ethics. In 2017 I was appointed as an Extraordinary Professor in the Department of Medicine, Faculty of Medicine & Health Sciences, Stellenbosch University.
Postgraduate Diploma in Health Research Ethics: Graduates 2015

**Dr Dudu Jankie**  
BA (Hum) & C.D.E, MSc (Ed), PhD.  
I continue to serve as a member of the University of Botswana Institutional Review Board (UB-IRB), I am also the Vice chairperson of the University of Botswana Institutional Review Board (IRB): Socio-Behavioural Sub-Committee. I am a member of the Interim Committee that has been working on a proposal for the establishment of the Centre for Applied Ethics and Bioethics at the University of Botswana.

**Assoc Prof Gordon Wayne Towers**  
BSc, BSc (Hons), MSc, PhD.  
Since completing the postgraduate diploma in 2015, I became chairperson of the Health Research Ethics Committee and advisory member for the AnimCare committee within the Faculty of Health Sciences at the North-West University or NWU (Potchefstroom Campus). I am also a member of the Institutional Research Ethics Regulatory Committee. I was also invited to be a panel member for the consensus study on: Ethical, Legal and Social Issues related to Human Genetics and Genomics in South Africa instituted by the Academy of Science of South Africa (ASSAf). In 2016, I was fortunate to be partly supported by the ARESA program to attend and present at the 13th World Congress of the International Association of Bioethics in Edinburgh, Scotland. Last year, I became the vice-chairperson of the steering committee for the newly established Research Ethics Committee Association of South Africa (REASA). I was also promoted to Associate Professor in January 2017.

**Dr Shenuka Singh**  
B.Oral Health, M.Sc [Dentium], PhD.  
I was appointed as Acting College Dean - Teaching and Learning, in the College of Health Sciences (February 2016 - March 2017), University of KwaZulu-Natal. In addition I have been appointed as a member on the National Health Research Ethics Council (NHREC) of South Africa (2016-2019).

**Dr Retha Visagie**  
Bcur, BaCur, BaCur Hons, Magister Curationis, Doctor Curationis.  
I participated in the Advancing Research Ethics Training in Southern Africa (ARESA) programme during 2015. I am responsible for the institutional management of research ethics and integrity at the University of South Africa since 2014. I am the chairperson of the Research Ethics Committee Association of Southern Africa (REASA). REASA is an initiative arising from the ARESA programme. The establishment of REASA, the first membership association of this kind in Southern Africa, signifies an extension of the ARESA agenda by focusing on the need to merge the isolated spaces in which individual research ethics committees from across the region currently operate. My engagement with REASA culminated in
collaboration with the Southern African Research and Innovation Management Association (SARIMA). I have co-facilitated a research ethics governance workshop during the SARIMA conference in 2016. Since then, I have offered a number of research ethics training workshops for universities in South Africa. I have recently embarked on a co-editorial book project with a focus on research ethics and integrity governance in Africa. I have co-published two articles focusing on research ethics since my participation in the ARESA programme. I am a member of the Organising Committee of the 6th International Conference on Ethics Education that will be held at Spier in 2018.

Mr Lemphi Mayoyo Moremi
BA (Social Science, MSc (Biostatistics & Epidemiology).
I am an active member of the Health Research and Development Committee (HRDC) and University of Botswana Research Ethics Committee (UB IRB). I am now employed as the Principal Research Officer at the Ministry of Health, Botswana.

Ms Melody Shana
BSc (Biological Sciences & Geography), Diploma (Clinical Trial Monitoring).
I currently serve as a Compliance/Research Officer within the Medical Research Council of Zimbabwe Secretariat for the past six years. I am mainly responsible for servicing the National REC hosted by MRCZ. I also assist in running Research Ethics and GCP courses offered by the MRCZ. I graduated in December 2016 and I am still at MRCZ and I am still carrying out the same duties I used to before ARESA.

Dr Gonasagrie Nair
MBChB, Diploma in Child Health, Diploma (Tropical Medicine and Hygiene), MPH.
I am a clinician with experience in managing HIV and TB co-infected patients in the South African public health sector and in a research setting. I was a Senior Research Clinician at the Centre for AIDS Programme of Research in South Africa (CAPRISA). Over the last few years, I have focused on the field of microbicides and was PI for NIH funded Microbicide Trial Network studies which have included the VOICE and ASPIRE Studies at the CAPRISA eThekwini clinical research site. I was also appointed protocol chair for the MTN 014 study. These roles have provided me with insight and experience in the conduct of microbicide and PrEP research. Since graduating from the ARESA program I have served on the UKZN REC and the REC of the South African MRC. I am currently working at the Desmond Tutu HIV Centre in Cape Town.
Ms Babazile Shongwe
Diploma in General Nursing, Diploma in Midwifery, Degree in Nursing.
I have been involved with the health sector for 14 years, having worked for Good Shepherd mission hospital as a Nurse, the Mbabane Government Hospital as a Senior Nurse Clinician and the Mbabane Public Health Unit as a Community Nurse. I am currently working as Research Officer in the Ministry of Health within the Research Unit. I serve as Secretary of the Swaziland Ethics Committee. I have led the process of developing the National Health Research Policy, National Health Research Strategic Plan and National guidelines for researchers as well as participating in development of the National Health Sector strategic Plan (NHSSP).

Ms. Imot Stella
BA in Social Work, PG Dip (Leadership & Management).
I am currently an IRB Administrator for the Makerere University School of Health Sciences Research and Ethics Committee in Uganda. I was awarded a scholarship to pursue training and internship at the NIH Department of Bioethics, Bethesda, Washington DC, in July 2012.

Prof Francis Rakotsoane
Bachelor of Philosophy, Master of Social Science, Ph.D.
There are several things that have happened since my graduation in 2015 as an ARESA Fellow. I have had an honour of being invited to contribute a chapter in a book that looks at research ethics from an African perspective and of presenting a paper titled “Professional Ethics and Trauma” at the Lesotho Medical Association Symposium organized in 2016, Maseru, Lesotho. I am also a Chairperson of a special committee mandated to draft a University-wide research policy for the National University of Lesotho with special emphasis on ensuring that observance of research ethics principles is enhanced across the University spectrum. I am currently working on a PhD proposal, provisionally titled: “Biobanking in sub-Saharan Africa: Potential Cultural Challenges, their Philosophical Underpinnings and Management.” The work is meant to have me registered for a doctoral degree in Biomedical Ethics sometime this academic year in the Centre for Applied Ethics, University of Stellenbosch.

Dr Beatrice Amugune
BPharm, MPharm, PhD.
I have continued to serve as a member, Kenyatta National Hospital - University of Nairobi Ethical Review and Research Committee. In addition, from January 2016, I was appointed a member, Kenya Medical Research Institute (KEMRI) Scientific and Ethics Review Unit (SERU) Committee. The Kenya Medical Research Institute is a state corporation responsible for carrying out health research in Kenya. As part of activities in these institutions I have severally been involved as a trainer in trainings on ethics and responsible conduct of research. From the ARESA project a publication was realised (B K Amugune, G C Verster. Knowledge and attitude of postgraduate students in Kenya on ethics in mental health research. S Afr J Bioethics Law 2016; 9(2):65-68).
Eshetu Worku
B.A in Economics, PhD, Pg Dip in International Health Economics & Pharmaeconomics.
I am currently employed as the Research and Development Director of at the Northern Cape Department of Health, South Africa. I have a PhD in Economics from University of the Western Cape, in South Africa; MS degree in Health Economics from Barcelona Business Management School and MS in Monetary Economics from Aligarh Muslim University in India. BA degree in Economics from Addis Ababa University, in Ethiopia. I have experience in undergraduate and post graduate teaching at different Universities. I serve the Provincial Heath Research and Ethics Committee as a chairperson.

Mr Pandeni Tshifugula
BSc (Nursing), PG Dip (Public Health), Masters (Public Health), Diploma Nursing, Master of Bioethics.
Since graduating, I formed part of the task force that reviewed the research ethics policy as well as the research ethics guidelines and regulations of the University of Namibia. In 2016 I also participated in the workshop that finalized the research ethics policy and guidelines of the University of Namibia. I continue to teach ethics to full time nursing students, and in 2016 my teaching of ethics has been extended to include the teaching of postgraduate nursing students who are studying on a distance mode. Starting 2016 I was also given the responsibility of teaching public health ethics to students doing master's in public health. I was appointed a member of the Indigenous Knowledge Council of Namibia since 2015 for a period of three years. I just obtained permission from the Center for Research and Publication of the University of Namibia at the end of 2016, and I am now busy drafting the research article for publication of the findings of my study I conducted through ARESA in 2015.

Ms Mercy Mbewe
BSc (Nursing), Masters (Educ), Diploma of Nursing Education.
I am currently employed as Coordinator of Health Management Programmes, at the National Institute of Public Administration, which involves developing curricula for new programmes and tailor made courses for the health sector. I am the institution's team lead for Management and Leadership Programme (2015-2018) for Health facility managers in the Ministry of Health in conjunction with USAID/ SBH/BRITE. Since graduating from the ARESA programme I have been appointed by the institute to establish a Research Ethics Committee and to co-ordinate Undergraduate research projects. Appointed member of Professional Conduct Committee of the General Nursing Council. I have completed development of a 4 year BSc Nursing Competency Based curriculum for North Rise University for implementation in 2017.
<table>
<thead>
<tr>
<th>Country</th>
<th>Graduates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botswana (3)</td>
<td>Mrs Tumalano Sekoto&lt;br&gt;Dr Dudu Jankie&lt;br&gt;Mr Lemphi Moremi</td>
</tr>
<tr>
<td>Ethiopia (3)</td>
<td>Dr. Beyene Ademe&lt;br&gt;Dr. Liya Dubale&lt;br&gt;Dr. Geremew Tsegaye</td>
</tr>
<tr>
<td>Kenya (4)</td>
<td>Dr. Christine Wasunna&lt;br&gt;Dr Beatrice Amugune&lt;br&gt;Prof Walter Jaoko&lt;br&gt;Dr. Lilian Omutoko</td>
</tr>
<tr>
<td>Lesotho (1)</td>
<td>Prof Francis Rakotsoane</td>
</tr>
<tr>
<td>Malawi (2)</td>
<td>Dr. Patrick Kamalo&lt;br&gt;Prof Fanuel Lampiao</td>
</tr>
<tr>
<td>Namibia (1)</td>
<td>Mr Pandeni Tshifugula</td>
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</table>
| South Africa (19) | Dr Nanette Briers<br>Prof Gordon Towers<br>Dr Retha Visagie<br>Dr Shenuka Singh<br>Dr Eshetu Worku<br>Dr Gonasagrie Nair<br>Dr Anna-Marie Wium<br>Adv Jamwell Maswangan
|              | yi Mr Thabo Molebatsi<br>Prof Blanche Pretorius<br>Prof Pramanathan Govender<br>Prof Ashley Ross<br>Dr Tyson Welzel<br>Mrs Tanya Coetzee<br>Prof Joyce Tsoka-Gwegweni<br>Prof Minrie Greeff<br>Dr. Ronelle Leech<br>Prof Brenda Morrow<br>Dr. Sunita Potgieter |
| Swaziland (1) | Ms Babazile Shongwe                                                      |
Uganda (3)

Jane Nabbuto
Ms Stella Imot
Dr. Tusubira Evans

Zambia (2)

Dr. Alwyn Mwinga
Sabina Luputa

Zimbabwe (2)

Mr George Chingarande
Ms Melody Phiri-Shana

TOTAL NUMBER OF ARESA-FUNDED TRAINEES: 41
TOTAL NUMBER OF COUNTRIES TRAINED: 11

ARESA RESEARCH ETHICS SEMINAR: 2012 – 2016

The ARESA Research Ethics Seminar has become an annual academic event on the Research Ethics calendar in Southern Africa over the past 5 years. Over 540 delegates have attended our annual ARESA Seminar over the past 5 years from various South African institutions as well as from Kenya, Ethiopia, Uganda, Malawi, Zambia, Nigeria, Namibia, Lesotho, Zimbabwe, Malawi, Botswana and Ethiopia. A wide range of stimulating talks were delivered by various South African speakers (Prof Anton Van Niekerk, Prof Keymanthri Moodley, Prof Himla Soodyall, Prof Anne Pope, Prof Akin Abayomi, Prof Johann Schneider, Dr Malcolm de Roubaix, Ms Melany Hendricks, Ms Ann Strode, Dr Laila Asmal, Dr Stefan Du Plessis, Prof Moodley, Dr Tina Malan, Dr Blanche Pretorius, Prof Marc Blockman, Dr Theresa Rossouw and Prof Marc Cotton). International speakers hailed from the USA (Prof Stuart Rennie, Prof Arlene Davis, Prof Dan Nelson and Prof Eric Jeungst), Zimbabwe (Mr George Chingarande), Australia (Prof Michael Selgelid), the WHO (Dr Abha Saxena and Dr Godwin Enwere), the San Rights Council (Mr Keikabile Mogodu), University of Utrecht (Prof Hans van Delden) and National University of Singapore (Dr Calvin Ho and Ireland (Dr Ciara Staunton), Uganda National Council for Science and Technology, Uganda (Dr Julius Ecuru), Kenya (Prof Walter Jaoko) and University of Ibadan, Nigeria (Michael Igbe).
OVER THE PAST 5 YEARS THE FOLLOWING TOPICS WERE DISCUSSED

2012:

• Biospecimens, Biobanks, Export Permits & MTAs
• Genetic Research and Ethics
• HIV Prevention Research: Controversies & Complexities
• Research Integrity

2013:

• Interpreting the Investigator’s Brochure: animal studies and early phase research
• Biobanking in Africa
• Research related injuries and compensation
2014:
• Research on Children
• Ethics & Genetic Research
• Reviewing Biobanking Protocols
• Neuroethics

2015:
• Authentic Community Engagement in Research
• Biobanking
2016:
• Serious Adverse Events in Research
• Ethics & Emerging Technologies
• Global Research Ethics
PUBLICATIONS:

Publications by ARESA Graduates
(ARESA graduates indicated by bold type)

2014


Abstract: The Emanuel, Wendler, and Grady framework was designed as a universal tool for use in many settings including developing countries. However, it is not known whether the work of African health research ethics committees (RECs) is compatible with this framework. The absence of any normative or empirical weighting of the eight principles within this framework suggests that different health RECs may raise some ethical issues more frequently than others when reviewing protocols. We used the Emanuel et al. framework to assess, code, and rank the most frequent ethical issues considered by a biomedical REC during review of research protocols for the years 2008 to 2012. We extracted data from the recorded minutes of a South African biomedical REC for the years 2008 to 2012, designed the data collection sheet according to the Emanuel et al. framework, and removed all identifiers during data processing and analysis. From the 98 protocols that we assessed, the most frequent issues that emerged were the informed consent, scientific validity, fair participant selection, and ongoing respect for participants. This study represents the first known attempt to analyze REC responses/minutes using the Emanuel et al. framework, and suggests that this framework may be useful in describing and categorizing the core activities of an REC.

2015


Abstract: The use of a Community Advisory Board (CAB) is one method of ensuring community engagement in community based research. To identify the process used to constitute CABs in Zambia, this paper draws on the perspectives of both research team members and CAB members from research groups who used CABs in Lusaka.


Abstract: Medical care of critically ill and injured infants and children globally should be based on best research evidence to ensure safe, efficacious treatment. In South Africa and other low and middle-income countries, research is needed to optimise care and ensure rational, equitable allocation of scarce paediatric critical care resources. Ethical oversight is essential for safe, appropriate research conduct. Informed consent by the parent or legal guardian is usually required for child research participation, but obtaining consent may be challenging in paediatric critical care research. Local regulations may also impede important research if overly restrictive. By narratively synthesising and contextualising the results of a comprehensive literature review, this paper describes ethical principles and regulations; potential barriers to obtaining prospective informed consent; and consent options in the context of paediatric critical care research in South Africa.

Abstract: The amended research ethics policy at a South African University required the ethics review of undergraduate research projects, prompting the need to explore the content and teaching approach of research ethics education in health science undergraduate programs. Two qualitative data collection strategies were used: document analysis (syllabi and study guides) and semi-structured interviews with research methodology coordinators. Five main themes emerged: (a) timing of research ethics courses, (b) research ethics course content, (c) sub-optimal use of creative classroom activities to facilitate research ethics lectures, (d) understanding the need for undergraduate project research ethics review, and (e) research ethics capacity training for research methodology lecturers and undergraduate project supervisors.

2016

Moodley K, Singh S. "It's all about trust": reflections of researchers on the complexity and controversy surrounding biobanking in South Africa. BMC Medical Ethics 2016, 17:57.

Abstract: Biobanks are precarious situated at the intersection of science, genetics, genomics, society, ethics, the law and politics. This multi-disciplinarity has given rise to a new discourse in health research involving diverse stakeholders. Each stakeholder is embedded in a unique context and articulates his/her biobanking activities differently. To researchers, biobanks carry enormous transformative potential in terms of advancing scientific discovery and knowledge. However, in Africa, researchers must balance the scientific imperative of collecting, storing and sharing high quality biological samples with obligations to donors/participants, communities, international collaborators, regulatory and ethics authorities. To date, researcher perspectives on biobanking in South Africa have not been explored and documented.


Abstract: Although clinical research in oncology is vital to improve current understanding of cancer and to validate new treatment options, voluntary informed consent is a critical component. Oncology research participants are a particularly vulnerable population; hence, therapeutic misconception often leads to ethical and legal challenges. We conducted a qualitative study administering semi-structured questionnaires on 29 adult, Phase 3, oncology clinical trial participants at three different private oncology clinical trial sites in South Africa. A descriptive content analysis was performed to identify perceptions of these participants regarding Phase 3 clinical trials. We found that most participants provided consent to be included in the trial for self-benefit. More than half of the participants had a poor understanding of Phase 3 clinical trials, and almost half the participants believed the clinical trial did not pose any significant risk to them. The word “hope” was used frequently by participants, displaying clear optimism with regard to the clinical trial and its outcome. This indicated that therapeutic misconception does occur in the South African oncology research setting and has the potential to lead to underestimation of the risks of a Phase 3 clinical trial. Emphasizing the experimental nature of a clinical trial during the consent process is critical to address therapeutic misconception in oncology research.

Abstract: A significant number of medications that are prescribed by doctors to treat cancers, tuberculosis and infections are ototoxic. Disclosure of ototoxic risks is ethical practice as patients have the right to be properly informed about and involved in decisions about their health care. Often, doctors fail to disclose such information. This research investigated whether a group of doctors working in a South African academic hospital inform their patients about the ototoxic risks associated with specific medications, and if not, explore the reasons for it. It was determined what the participants’ knowledge levels of ototoxicity were as knowledge is seen as a precursor to disclosing information to their patients. A further aim of the research was to determine whether audiologists should expand their role by sharing information with patients and other professionals in the management of ototoxicity and in the hospital.


Abstract: Most people with mental illness live in developing countries, where a large proportion of these illnesses are undiagnosed and untreated. As effort is made to encourage mental health (MH) research as an avenue to optimise the management of mental illness, this should be accompanied by adequate knowledge, correct attitude and practice on ethical conduct of research. This study reports the knowledge and attitude among postgraduate students in Kenya on ethics in MH research.


Abstract: Over the past decades there have been tremendous efforts to improve the ethical conduct of research involving humans throughout the world. As a one-size-fits-all philosophy can no longer work, most countries have developed specific legal and ethical guidelines for research, tailored to their own context. We reviewed South African (SA) ethical guidelines and Health Research Acts as they pertain to the role of caregivers in consent practices for minors’ participation in HIV/AIDS-related research.


Abstract: Compensation for research-related injuries (RRIs) remains a challenge in the current environment of global collaborative biomedical research as exemplified by the continued reluctance of the US government, a major player in international biomedical research, to enact regulation for mandatory compensation for RRIs. This stance is in stark contrast to the mandatory compensation policies adopted by other democracies like the European Union (EU) countries. These positions taken by the USA and the EU create a nexus of confusion when research is exported to low-income and middle-income countries which have no laws guiding compensation for RRIs. In this paper, we begin by exploring the background to policies concerning RRIs, how they reflect on the traditional dispute resolution mechanisms in African societies, and how this compares with the no-fault compensation model. We then explore the underlying African ethical framework of Ubuntu in the sub-Saharan region, guiding traditional practices of dispute resolution and compensation, and how this framework can help to form the moral justification for no-fault compensation as the preferred compensation model for RRIs for African countries. Finally, we call upon countries in the African Union (AU), to adopt a no-fault policy for compensation of RRIs, and enact it into a regulatory requirement for insurance-based no-fault compensation for biomedical research, which will then be enforced by member states of the AU.

Abstract: The effective functioning of a research ethics committee (REC) can be evaluated using self-assessment tools. The Middle East Research Ethics Training Initiative (MERETI) tool can be used by one member, typically the Chair, to score an REC. The consistency of these scores across several members of an REC has never been evaluated. This study examined whether results would be consistent irrespective of who conducts the assessment. One REC’s effective functioning was assessed by several members (n = 13). The Chair’s scores were compared with scores of other members in relation to their duration of REC membership, research ethics training, gender, and employer’s institutional affiliation to the REC. The Chair’s overall score was higher than the other members’ scores by 11%. No significant differences in scores were obtained in relation to duration of REC membership (p = .72), interval since last research ethics training (p = .94), and gender (p = .27). The MERETI tool is thus consistent irrespective of who performs the assessment.


Abstract: Health researchers conducting research in the community are often faced with unanticipated ethical issues that arise in the course of their research and that go beyond the scope of ethical approval by the research ethics committee. Eight expert researchers were selected through extreme intensity purposive sampling, because they are representative of unusual manifestations of the phenomenon related to their research in the community. They were selected to take part in a semi-structured focus group discussion on whether practical wisdom (phronesis) is used as a decision-making skill to solve unanticipated ethical issues during research in the community. Although the researchers were not familiar with the concept phronesis, it became obvious that it formed an integral part of their everyday existence and decision making during intervention research. They could balance research ethics with practical considerations. The capacity of practical wisdom as a crucial decision-making skill should be assimilated into a researcher’s everyday reality, and also into the process of mentoring young researchers to become phronimos. Researchers should be taught this skill to handle unanticipated ethical issues.

2017


Abstract: Chapter 8 of the South African National Health Act 61 of 2003 (NHA) that deals with the donation of human tissue was promulgated in 2012. The new Act is perceived to impose restrictions on low-risk research involving human remains. This study aimed to identify the issues raised by a research ethics committee (REC) when reviewing protocols where human remains are used as data source. REC minutes from 2009 to 2014 were reviewed, and issues raised by the committee were categorized. In total, 127 protocols submitted to the committee over 6 years involved human remains. Queries relating to science (22.2%) and administration (18.9%) were the most common, whereas queries relating to legal issues constituted only 10.2%. Ethical issues centered on informed consent regarding sensitive topics such as HIV, DNA, and deceased children. The change in legislation did not change the number or type of legal issues identified by the REC.
ACKNOWLEDGEMENTS

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We wish to thank the following people

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Grants Office
Mr Eugene Baugaard

Executive Head, Department of Medicine, Faculty of Medicine & Health Sciences, Stellenbosch University
Prof Rafique Moosa