



ARESA

ADVANCING RESEARCH ETHICS
TRAINING IN SOUTHERN AFRICA

Vol. 6 No 1

Dec 2016

Editors: Prof. Keymanthri Moodley, Centre for Medical Ethics & Law, Department of Medicine, Faculty of Medicine & Health Sciences, Stellenbosch University, South Africa
Prof. Stuart Rennie, Bioethics Center, University of North Carolina, Chapel Hill (USA)

Dear REC Members,

After 5 wonderful, exhilarating years, the ARESA educational program came to an end in December 2015. Our last trainee graduated in December 2016, bringing our capacity development effort to a total of 40 graduates from 10 different African countries. We are all extremely proud of this achievement! We are also extremely proud of our graduates who have soared to great heights both in their personal career paths and on national research ethics bodies. The Research Ethics Association of Southern Africa (REASA) – almost completely graduate driven at this stage - has also been making great strides and membership is growing.

The ARESA program has been extremely productive in terms of publications. You will find links to these in the relevant section of this newsletter. We look forward to involving our graduates in future projects as collaborators, supervisors, mentors and faculty.



We wish you all a safe and joyous festive season and look forward to continuing our conversations and deliberations around research ethics in 2017.

Keymanthri Moodley and Stuart Rennie

*Principal Investigator: Prof Keymanthri Moodley,
Centre for Medical Ethics and Law
Faculty of Health Sciences, University of Stellenbosch
Co-PI: Prof Stuart Rennie, Center for Bioethics,
University of North Carolina, Chapel Hill, United States*





ARESA

ADVANCING RESEARCH ETHICS
TRAINING IN SOUTHERN AFRICA

HIGHLIGHTS FROM THE 5th ANNUAL ARESA RESEARCH ETHICS SEMINAR

20 May 2016

This year 100 delegates from various South African RECs attended our annual seminar and we were pleased to welcome back ARESA Alumni. A wide range of stimulating talks were delivered by South African speakers (Prof Anton Van Niekerk and Prof Keymanthri Moodley). International speakers hailed from the USA (Prof Stuart Rennie), Zimbabwe (Mr George Chingarande), Australia (Prof Michael Selgelid), Scotland (Dr Gill Black) and Ireland (Dr Ciara Staunton).



*Principal Investigator: Prof Keymanthri Moodley,
Centre for Medical Ethics and Law
Faculty of Health Sciences, University of Stellenbosch
Co-PI: Prof Stuart Rennie, Center for Bioethics,
University of North Carolina, Chapel Hill, United States*

Communicating complex science to the public in a shared ethical space

Dr Gill Black

Dr. Gill Black, a director at the Sustainable Livelihoods Foundation (SLF), joined us as a speaker at the 5th annual ARESA seminar in May. Gill shared her insights about the array of communication methods and approaches that can be undertaken to communicate complex science to the public. She gave multiple examples of initiatives taken recently by South African scientists, research clinicians and health professionals to inform and engage the public in scientific exploration; popular books created to engage children in the exciting findings of palaeontology, video that uses a story-based approach to describe and illustrate the current status of research seeking a cure for HIV; high school 'science spaza' clubs that involve scientists assisting youth in the design of action research projects to understand and address issues of water security and water related diseases – using Hip Hop and Rap music as a community uptake strategy.

Dr Black then provided an overview of a current community engagement project being undertaken by SLF, supported by a Wellcome Trust International Engagement Award that she won in early 2016.



Gill described an ethical dilemma that had bubbled up through this work, and how it opened up a new way of thinking for her and her team regarding the vulnerabilities of all participants involved in interactive public communication efforts. She emphasized that good communication is a 2-way process and that true engagement happens when those who are in conversation have equal voices and are enabled to listen to and hear each other in a shared, level space. Gill left us with 2 questions which she feels need to be considered especially by engagement practitioners, research funders and the wider scientific community: How can the valuable knowledge of the public be better used to ground and inform biomedical research. How can scientists be better supported to involve themselves more meaningfully in community engagement, to show their humanity and bridge the trust gap that exists between them and the general public?

A comparative narrative of the compensation policies for research related injury in Brazil, Russia, India, China and South Africa (BRICS)

Mr George Chingarande

Compensation for research related injuries is a subject that is increasingly gaining traction in developing countries burgeoning destinations of multi center research. However, the existence of disparate compensation rules violates the ethical principle of fairness.

The presentation was a synopsis of a comparison of the policies of Brazil, Russia, India, China and South Africa (BRICS) and the implications for RECs.

The study revealed that there is vast panoply of regulations which exist on a continuum. On one extreme is India with comprehensive regulations replete with time lines that are codified into law,

and on the other end there is China which does not have specific laws regulating research related injuries but relies on product quality laws. Indian regulations require the REC to give recommendations on the quantum of compensation. RECs must therefore equip their members with skills that make it possible for them to execute these extra responsibilities and also ensure that researchers capture additional data, such as income, required in determining the quanta of compensation. Brazil regulations provide for both comprehensive medical care and the right to compensation which cannot be waived away by the participants. In Russia the researcher must insure all research participants. The regulations also stipulate how much should be paid out depending on the degree of injuries. However, normal insurance terms and conditions apply and courts can vary the amounts of compensation. The South African regulations require that the sponsor should insure the research participants.

Comprehensive medical care should be provided to participants who suffer injuries. However, compensation is not mandatory but RECs should ensure that participants are fully canvassed on the existence or absence of compensation arrangements.

There is need for consistency and ideally harmonization of regulations at a global level. A model policy on compensation for research related injuries should borrow from the best aspects of the different country policies and should be informed by the cardinal ethics principles of autonomy, justice and beneficence.

“Playing God” or advancing science - New Bio Technologies in the 21st Century

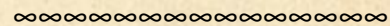
Prof Anton Van Niekerk,

The new biotechnologies we are seeing in the 21st century are indicative of our increasing ability to take our evolution as a species into our own hands. The question is whether we can do that responsibly without relapse into the Frankenstein or Prometheus dangers that accompany such developments. A number of examples of these new technologies were mentioned. The discussion started with noting the “simple conservative argument” often brought in against these new technologies. Buchanan’s formulation of this argument is: “Biomedical enhancements carry extraordinary risks, and given how well off we already are (thanks in part to past enhancements) those risks are not worth taking. So even if we could have been wrong – indeed stupid – to have forgone the major historical enhancements, we should draw the line now” (Buchanan 2011: 55). Buchanan himself rejects this argument, which in different disguise is also offered by people like Habermas, Fukuyama, Kass and Sandel. In response, Van Niekerk argued that it is utterly unclear why it would be desirable to arrest human evolution at the point where a measure of control over the process is attained. One often always hears the argument:

“Nature knows best; don’t interfere! How seriously can this be taken? Does “nature also knows best” with reference to diseases such cancer, diabetes, cystic fibrosis, etc.? The author noted the role that (technologically and otherwise driven) enhancements have played to get us where we currently are: vaccinations, dialysis, advanced anaesthetics, cat scans, literacy, institutions. A number of areas were identified that will in future only be managed by means of biomedical enhancements of humans. Attention was also paid to the problems surrounding the idea of moral enhancements. Sandel’s views were also subjected to criticism. The author concluded by asking why scepticism so often seems to be the “natural” response to the changes foreseen by applying biomedical technologies.

Suppose the dead of 300 years ago arise and contemplate our world. Think how silly we would regard it if they were to tell us that the mere thought of cars, telephones, TV’s, space travel or cures for cancer and pneumonia were possibilities! We have always explored new terrain, ignorant of all the (good and bad) consequences to which it c/would lead. Compare the positive effects of industrialisation (food production, division of labour, large scale production and wealth) – with yet negative effects (pollution, exploitation). Compare the marvellous consequences of aviation (immeasurably increased mobility, speed and safety of travel) - with yet negative effects (danger, destructive role in warfare [bombings], spread of infectious disease, etc.) Compare the benefits of nuclear power (cleaner energy, much more capacity) – with possible serious negative effects, e.g. total destruction of planet via nuclear war.

The point is: None of these things – including new biomedical technologies – are wholly good or bad, desirable or undesirable in themselves. Very few things in life are intrinsically good or bad. Each development/manifestation needs to be evaluated in its own terms, piecemeal. This calls for an ethics of responsibility.



BRIEF REPORT FROM RESEARCH ETHICS WORKSHOP HELD AT AHRI

Dr Liya Wassie ARESA Alumnus 2013



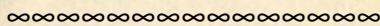
A refresher workshop on research ethics was initially proposed by members of the Armauer Hansen Research Institute/All Africa Leprosy and Tuberculosis Rehabilitation and Training Center (AHRI/ALERT) ethics review committee (AAERC).

This is a recognized institutional review board (IRB) in Ethiopia, accredited by the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) (WHO/TDR).

The AAERC selected some important and current topics in the area of research ethics, including 'vulnerability and risk-benefit assessment in conducting medical research', 'reviewing clinical trials', 'reviewing social and behavioral studies', 'reviewing genetic studies' and 'data sharing and biobanks'.

The main aim of the workshop was to update REC members on current issues in research ethics and enrich their knowledge through discussion and networking as part of continuous professional development.

The training was conducted by prominent individuals in research ethics and genetic research including, Prof Keymanthri Moodley from Stellenbosch University, South Africa, Prof Gail Davey from Brighton and Sussex Medical School, the UK and Dr. Adam Gilbertson from University of North Carolina, USA. A total of 34 representatives attended the workshop from different research institutions, university IRBs and regulatory bodies in Ethiopia. Dr. Liya Wassie, who is one of the AAERC members and an ARESA graduate from University of Stellenbosch, took the responsibility in leading the initiative and organized the event. All financial expenses related to the training was covered by core funding from AHRI.



REASA STEERING COMMITTEE: STRENGTHS, OPPORTUNITIES, ASPIRATIONS AND RESULTS

The Research Ethics Committee Association of Southern Africa (REASA) was launched on 17 September 2015. The REASA steering committee engaged in critical activities since the launch to ensure that REASA fulfils its promise of being an independent multidisciplinary membership association

'Connecting research ethics committees in Southern Africa'. Some of these activities include:

- The finalisation of the constitution based on consultation with legal stakeholders.
- Opening of the REASA bank account and the commencement of membership registration.
- Engagement with representatives from the Southern African Research and Innovation Management Association (SARIMA) that culminated in the offering of a pre-conference workshop as part of the 2016 SARIMA conference. In addition, the collaboration resulted in a theme on research ethics and integrity that was added to the conference programme. The workshop created active interest and was well received by the research management audience across Southern Africa.
- The steering committee recently embarked on a SOAR analysis as a first step to develop a strategic plan. The acronym SOAR stands for: **S**trengths, **O**pportunities, **A**spirations, and **R**esults. A SOAR analysis is a positive approach to strategic thinking and planning that explores current strengths, opportunities, aspirations and expected results required by an organisation to achieve its intended future ¹. The findings of the SOAR analysis revealed the committee's belief that REASA is well positioned to assess and respond to the diverse needs of human and animal research ethics committees (HRECs and ARECs) in Southern Africa. REASA aims to provide a platform for dialogue and communication and to support REC's through research ethics capacity building, networking, consultation and collaboration.

¹ Stavros, JM & Hinrichs, G (2009). The Thin Book of SOAR: Building Strength-based strategy. Thin Book Publishing Co.

- The committee recognises the importance to seek input from a wide range of stakeholders to foster open, representative and inclusive decision-making. Ongoing engagement with members and stakeholders was identified as a critical measure to ensure that goals remain aligned with the identified needs of members.

The immediate plan of action for the REASA steering committee includes the following:

1. Plan and coordinate the first Annual General Meeting in tandem with the ARESA seminar on 11 May 2017
2. Develop a communication and marketing plan
3. Keep an updated database of members and stakeholders
4. Identify possible sources of funding for sustaining REASA
5. Involve members in a similar needs analysis to determine the short and medium term focus of REASA

The REASA steering committee is primarily composed of previous ARESA alumni. Prof K Moodley and Prof S Rennie are ex officio members.

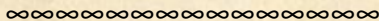


Join us on the REASA Facebook page

For more information contact:

secretary.reasa@gmail.com or Dr Retha Visagie:

Visagrg@unisa.ac.za



ARESA ALUMNI AT THE 13th WORLD CONGRESS OF THE INTERNATIONAL ASSOCIATION OF BIOETHICS

Dr Wayne Towers



Attending the 13th World Congress of the International Association for Bioethics (IAB) held at the Edinburgh International Conference Centre in Scotland from the 14-17 June 2016, was definitely an eye-opening experience for me. As a natural scientist stepping into an arena that has its roots in philosophy and the social sciences, I must say that I was initially a little intimidated by the large spectrum of topics that were being presented at IAB2016, but I soon realised that as Marcel Proust says, “We don't receive wisdom we must discover it for ourselves,” and as such, I got stuck in and attended as many of the sessions as I possibly could. The major theme of the congress was, “Individuals, Public Interests and Public Goods: What is the Contribution of Bioethics?” and this theme was apparent in many of the lectures that I attended, from the initial keynote lectures presented, (which dealt with Bioethics and Legislation as well as possible preventative measures to counter the brain drain in developing countries) during the official opening right through to the final keynote given by Baroness Onora O’Neill on “Public goods and private data”.

The other major theme of the conference was the specific focus on Art and Ethics, which highlighted extremely novel but immeasurably relevant approaches to making the field of ethics accessible to the greater public, and ensuring that we retain our humanity in the face of our highly academic discourse in this field.

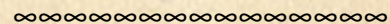
I also took many lessons from these presentations for the design and implementation of future science education opportunities in my own field of genetic and genomic research.

Although the entire conference was a wonderful experience, during which I attended numerous sessions on biobanking, ethics of genetic and genomic research and research in the developing world, a personal highlight for me was of course being included in the symposium entitled, "After Ebola: Challenges facing infectious diseases biobanking", which was very ably organised by Professors (Proffs) Calvin Ho and Keymanthri Moodley. During this session, I gave an oral presentation entitled, "Dissemination of both primary and incidental findings in research-driven genomic studies: Ethical implications for large-scale bio-banking of samples". Those in attendance were extremely interested and interactive during the discussion session. I, myself, was extremely grateful to be able to interact with such leaders in the field of ethical, legal and social implications of biobanking and genetic and genomic research as Proffs Ho, Moodley and Katherine Littler (session co-chair). In conclusion, I truly felt that my horizons were inexorably broadened by this conference, both in terms of the knowledge I gained as well as the networking opportunities that were afforded me. As such I would like to extend my deepest gratitude to Proffs Moodley and Rennie, as well as the ARESA program, and the Dean of the Faculty of Health Sciences, North-West University (Potchefstroom Campus), for financially contributing to this trip and making this a wonderful opportunity a possibility.

Prof Minrie Greeff



There is an apparent revival in both practice and research in the disciplines of education, law and health with regard to the use of Aristotle's notion of phronesis, also referred to as practical wisdom, one of the intellectual virtues in the *Nicomachean Ethics*. 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.



ARESA ALUMNI NEWS



Mr **Thabo Molebatsi** has been appointed as Director: Health Statistics at Statistics South Africa.



Ms **Babazile Shongwe** has been admitted to a Master of Science in Health Research Ethics in Kenya.



Dr **Tina Malan** recently published the work she completed during the ARESA programme entitled "Phase 3 Oncology Clinical Trials in South Africa: Experimentation or Therapeutic Misconception?" in the Journal of Empirical Research on Human Research Ethics.
<http://journals.sagepub.com/doi/pdf/10.1177/1556264616637736>



Dr **Patrick Kamalo** recently published the work she completed during the ARESA programme entitled "Appropriateness of no-fault compensation for research related injuries from an African perspective: an appeal for action by African countries" in the Journal of Medical Ethics.
<http://jme.bmj.com/content/42/8/528>



Prof **Minrie Greeff** recently published the work she completed during the ARESA programme entitled "Phronesis: Beyond the Research Ethics Committee — A Crucial Decision-Making Skill for Health Researchers During Community Research" in the Journal of Empirical Research on Human Research Ethics. She has also been appointed as a member of the National Health Research Ethics Council (NHREC) by the Minister of Health.
<http://journals.sagepub.com/doi/pdf/10.1177/1556264616650070>



Dr **Shenuka Singh** recently published the work she completed during the ARESA programme entitled "It's all about trust": reflections of researchers on the complexity and controversy surrounding biobanking in South Africa" in BMC Medical Ethics. She has also been appointed as a member of the National Health Research Ethics Council (NHREC).
<https://bmcomedethics.biomedcentral.com/articles/10.1186/s12910-016-0140-2>



Dr **Wayne Towers** has been promoted to Associate Professor at North-West University.



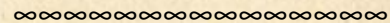
Prof **Walter Jaoko** recently published the work she completed during the ARESA programme entitled "An Evaluation of the Middle East Research Training Initiative (MERETI) Tool in Assessing Effectiveness of

Research Ethics Committees (RECs): Experience with a Kenyan REC" in the Journal of Empirical Research on Human Research Ethics. <http://journals.sagepub.com/doi/pdf/10.1177/1556264616665952>



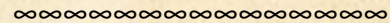
Dr **Beatrice Amugune** recently published the work she completed during the ARESA programme entitled "Knowledge and attitude of postgraduate students in Kenya on ethics in mental health research" in the South African Journal of Bioethics and Law.

<http://www.sajbl.org.za/index.php/sajbl/article/view/470/0>



BREAKING NEWS...

The revised CIOMS International Ethical Guidelines for Health-related Research involving Humans have now been finalized and adopted. The guidelines are available at: <http://www.cioms.ch/ethical-guidelines-2016/>



UPCOMING CONFERENCES & EVENTS

6th Annual ARESA Health Research Ethics Seminar (11-13 May 2017, Vineyard Hotel, Newlands)

8th South African AIDS Conference (13-16 June 2017, Durban, South Africa)

13th International Conference on Clinical Ethics Consultation (ICCEC) (25-27 May 2017, Singapore)

Oxford Global Health & Bioethics International Conference (17-18 July 2017, University of Oxford, United Kingdom)

9th IAS Conference on HIV Science (23-27 July 2017, Paris, France)

Public Responsibility in Medicine and Research (PRIMR), (6-8 November 2017, San Antonio, Texas)



Dr **Anna-Marie Wium** recently published the work she completed during the ARESA programme entitled "Ototoxicity management: An investigation into doctors' knowledge and practices, and the roles of audiologists

in a tertiary hospital" in the South African Journal of Communication Disorders. <http://www.sajcd.org.za/index.php/sajcd/article/view/174>



Dr **Eshetu Worku** recently published the work he completed during the ARESA programme entitled "A critical review of health research ethical guidelines regarding caregiver consent for HIV research involving minors in South Africa: Ethical and legal

issues" in the South African Journal of Bioethics and Law. <http://www.sajbl.org.za/index.php/sajbl/article/view/458/0>

NOTES

A series of horizontal dashed lines for writing notes, arranged in two columns across the page.