ARESA

ADVANCING RESEARCH ETHICS TRAINING IN SOUTHERN AFRICA

Vol. 3 No 2 **06 December 2013**

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

Dear REC Members

It is indeed an honour to be releasing the second issue of the 2013 ARESA newsletter today as we remember and bid farewell to an extraordinary leader, Nelson Mandela. In the world of Bioethics, he has taught us many poignant lessons about justice, courage, humility, sacrifice and forgiveness. These are the values we can carry with us in our ethics deliberations for many decades to come. Nelson Mandela has been an inspiration to us all.

To continue on this theme of inspiration, it gives me great pleasure to announce that all the ARESA trainees on the 2013 Postgraduate Diploma in Health Research Ethics program have successfully completed their training. Eight trainees will graduate in December 2013 (two cum laude: Dr Alwyn Mwinga and Prof Ashley Ross) and two trainees will graduate in March 2014. Dr Tina Malan (a 2012 trainee) will also graduate cum laude in December 2013. Dr Ronell Leech and Dr Beyene Ademe (2012 trainees) graduated in March 2013.

The 2nd Annual ARESA Research Ethics Seminar was held in September this year and it was a huge success. Approximately 120 delegates from South Africa and other African Countries attended and participated actively in vibrant discussion sessions.

We wish to extend a warm welcome to Dr Ciara Staunton who joined the Centre for Medical Ethics and Law as ARESA program co-ordinator in September. We also wish to express our appreciation to our administrative assistants, Meagan Leukes and Kelsey February, for their outstanding efforts in making the programme a success since its inception.

Best wishes for a peaceful and joyous festive season, Keymanthri & Stuart

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

UNIVERSITEIT STELLENBOSCH UNIVERSITY

UNC CENTER FOR BIOETHICS

ARESA

ADVANCING RESEARCH ETHICS
TRAINING IN SOUTHERN AFRICA

2014 ARESA TRAINEES

The ARESA Postgraduate Diploma in Health Research Ethics was advertised with Research Ethics Committees, academic institutions and other health institutions in South Africa and Southern Africa in 2013. Approximately 27 high quality applications were received and the ARESA Advisory Committee selected ten ARESA trainees for the 2014 academic year. The Diploma programme consists of three modules and a short research assignment. For more information on the Diploma programme visit www.sun.ac.za/aresa.

See below a short biosketch on each of the 2014 ARESA trainees.

Dr Anna-Marie Wium is a Senior Lecturer at the University of Limpopo (Medunsa Campus) where she has served on the Medunsa Research Ethics Committee for the past 4 years. Her current research interests are early childhood development (particularly child language development and emergent literacy), teaching and learning, as well as service-learning. She has a degree in Speech-Language Pathology and Audiology from the University of Pretoria and a Master's degree (cum laude) in Augmentative and Alternative Communication.

Dr Brenda Morrow is an Associate Professor in the Department of Paediatrics, University of Cape Town (UCT), South Africa.

A physiotherapist by training, Brenda worked clinically from 1995 to 2006 at Red Cross War Memorial Children's Hospital in Cape Town. She developed a special interest in paediatric respiratory diseases, particularly in the context of critical care and the management of children with Cystic Fibrosis, and embarked on a Master's Degree in 2001, which was upgraded to PhD in 2003, which she was awarded in 2005. Her current job description includes expanding the African Paediatric Fellowship Program to train paediatric allied health and rehabilitation therapists throughout Africa and to facilitate the concept of a multidisciplinary, holistic approach to child health practice and research. Brenda is Deputy Chair of the Departmental Research Committee; a member of the Faculty of Health Sciences Research and Human Research Ethics Committees; and a member of many special interest and advisory boards. She has published and presented her research findings widely, and won several awards. She is a regular reviewer for international journals.

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

UNIVERSITEIT STELLENBOSCH UNIVERSITY

UNC CENTER FOR BIOETHICS

Dr Fanuel Lampiao graduated from the University of Malawi, Chancellor College in 2001 and later received a MSc and PhD from Stellenbosch University. Dr Lampiao specialized in reproductive medical physiology with special interest in male infertility. He is currently an Associate Professor of Physiology at the College of Medicine, University of Malawi and holds the position of Dean of Students. His research interest is in reproductive physiology with special focus on reactive oxygen species measurement in human spermatozoa and how they affect fertilizing capability; effect of insulin, leptin and cytokines on human sperm function, and the development of a reversible oral herbal male contraceptive. Over the past few years he has generated data that have helped to better understand factors and conditions that necessitate normal functioning of human spermatozoa. This research has led to better diagnosis of male infertility in couples struggling to have children

Dr Farayi Moyana is the clinical director of Borrowdale dental surgery as well as Medical Chambers' Dental Centre in Harare. He is a member of the interim Research, Scientific and Publications sub-committee as well as being the Honorary Treasurer of the Zimbabwe Dental Association (ZIDA). He teaches on a part-time basis-Applied Oral Biology and preventive orthodontic science in the School of Dental Therapy and Technology in Harare. Dr Moyana has been the dental adviser for a leading Health Insurance company in Zimbabwe since 2006. He holds the following tertiary and academic diplomas and degrees: Bachelor of Dental Science (BDS) from MEDUNSA; Master of Public Health (MPH) (University of Limpopo), Bachelor of Adult Education (University of Zimbabwe), Master of Business Administration (MBA) from the Zimbabwe Open University, Postgraduate Diploma in Orthodontics (University of Pretoria); Diploma in Adult Education (UZ); Health Teachers Diploma (Mandel Training Centre); Executive Management Certificate; Dental Therapist Diploma.

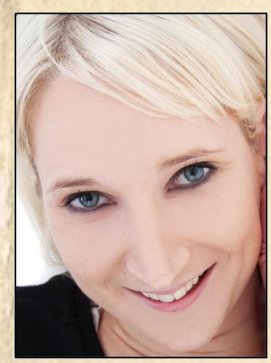
Mr George Rugare Chingarande is a lecturer at the University of Zimbabwe in the College of Health Sciences. He holds qualifications in Radiotherapy, Oncology, Nuclear medicine and is also a holder of an MBA degree from DeMontfort University, UK. He has been a fellow at the National Cancer Institute at the National Institutes of Health (Maryland, USA) and at the International Agency of Cancer Research (IARC, Lyon France) and a graduate of the Dundee University program in Global Health and Epidemiology. His research interests are in cancer epidemiology, molecular imaging and non-communicable diseases. Since 2008 he has focused his attention on biomedical ethics, human subjects' protections, and in the ethical conduct of human investigations involving the use of ionizing radiation. He has also participated in large scale national surveys such as the National TB Survey and Non Communicable Disease Risk Factor prevalence survey. He provides ongoing ethics consultation to researchers at the College of Health Sciences and also the Ministry of Health, Zimbabwe.

Dr Lillian Otieno-Omutoko is a Senior Lecturer in the Department of Extra Mural Studies, University of Nairobi, Kenya. She teaches Project Design and Implementation, Total Quality Management, Gender Issues in Development and Training & Curriculum Development and Research Methods. She has pursued a course in Monitoring and

Evaluation of Population and Health Programs. Her research activities include supervision of postgraduate students, carrying out research in education, gender, management and research ethics. She is the Deputy Chief Editor of African Journal for Project Planning and Management and a reviewer of Journals. She is a Social Scientist interested in bioethics and research ethics in which she has focused since 2010. She has particular interest in research and development, protection of human subjects and vulnerable populations. As an active member of University of Nairobi- Kenyatta National Hospital Ethics Research Committee, she has undergone training in Responsible Conduct in International Research and had exposure to Biomedical Ethics and Medical Ethics. She is certified by Collaborative Institutional Training Initiative (CITI) in Human Subjects Research and facilitates training of researchers, health practitioners and Ethics Research Committee members. She has experience in research regulatory activities including protocol review, development of Standard Operating Procedures and regulatory compliance. She has been involved in monitoring and evaluation of research sites, development of curricula and study modules for graduate students. She is a committee member of Research, Consultancy and Collaborations Committee

Dr Gonasagrie Nair is a clinician with with experience in managing HIV and TB co infected patients in the South African public health sector and in a research setting. She has a Diploma in Tropical Medicine and Hygiene at the University of Witwatersrand and later a Masters degree in Public Health at the University of KwaZulu Natal. She is currently Senior Research Clinician at Centre for AIDS Programme of Research in South Africa (CAPRISA). Over the last few years, she has focused on the field of microbicides and is currently the CAPRISA eThekwini clinical research site PI for NIH funded Microbicide Trial Network studies which have included the VOICE and current ASPIRE Studies. She was also appointed protocol chair for MTN 014 study, roles that have provided her with insight and experience in the conduct of microbicide and PrEP research.

Prof Minrie Greeff is Professor in research in the Africa Unit for Trans-disciplinary Health Research of the Faculty of Health Sciences at the North-West University, Potchefstroom campus since 2008. In the past few years she has focused her research effort on HIV and AIDS related aspects. She was project leader of two NRF grants and the primary investigator of SA in a five year NIH funded project. This was followed by a three year (2010 – 2012) SANPAD funded project. In 2011 she received NRF Blue Skies funding for innovative research in HIV stigma reduction at the community level. She was a member of the South African Nursing Council for five years. She was a member of the research committee (2005 – 2006) as well as elected director of the research committee and member of the board of directors of the "Tau Lambda-at-Large Chapter" of the Sigma Thetha Tau International Honor Society for Nurses from 2006 – 2008. In 2008 she became one of the National Research Foundation's rated researchers. She was invited by the World Health Organization in June 2009 to be on a team of experts that formulated guidelines for the disclosure of children's HIV status (published 2011). Prof Greeff has received numerous awards with the most recent the induction into the Researcher's Hall of Fame of the Forum of University Deans in South Africa (2011). She was nominated women of the year of the American Biographical Institute; inducted into the American Biographical Institute's Professional Hall of Fame (2011); and the most prestigious induction into the International Nurse Researcher Hall of Fame of Sigma Theta Tau International on the 2nd of August 2012 in Australia. She is an inducted member of ASSAf since 2012.



Dr Sunita Potgieter is a registered dietitian specializing in sport nutrition and nutritional status assessment. She has been a lecturer in therapeutic nutrition at the Faculty of Medicine and Health Sciences of Stellenbosch University Since 2007 and she has a private practice in Somerset West/Strand. Sunita completed her Master's Degree at the end of 2008 and graduated with her PhD during March 2013. Her main research focus areas include nutritional status assessment, nutritional supplementation and nutrition for physical activity. She has presented her research at national congresses and is currently serving on the Health Research Ethics (Vice-chair) And Wellness Committees (Chair) Of the Faculty of Medicine and Health Sciences, Stellenbosch University. She Is the facilitator for the sport nutrition module of the Master of Nutrition Degree at Stellenbosch University and lectures in this field at Honors Level at Stellenbosch University's Department Of Sport Science, as well as the University Of the Western Cape. She Is the Western Cape representative for the South African Sports Medicine Association (SASMA) and is part of the Association For Dietetics South Africa Sport Nutrition Working Group (ADSA---SNWG) a professional member of the American College For Sports Medicine (ACSM). She recently published a sport nutrition review article by invitation from the South African Journal of Clinical Nutrition (SAJCN). Sunita enjoys sport and is a triathlete herself. She has completed several Olympic and Ironman Distance events, earning an Ironman World Championship Slot in her age group in 2008.

Prof Walter Jaoko is a Professor of Medical Microbiology and Tropical Medicine, and the current Chairman of the Department of Medical Microbiology at the University of Nairobi. He is also the Deputy Director of Kenya AIDS Vaccine Initiative, a research centre of the School of Medicine, University of Nairobi, committed to research and development of a preventive HIV vaccine. Prof. Jaoko did his undergraduate medical training at the University of Nairobi where he graduated in 1986. He thereafter worked as a Medical Officer in the Ministry of Health of the Government of Kenya for three years before joining the University of Nairobi in 1989 on a staff development programme, as an Assistant Lecturer. He obtained his masters' degree in Tropical Medicine from Liverpool School of Tropical Medicine and Hygiene of the University of Liverpool in 1993 and a PhD in Medical Microbiology from the University of Nairobi in 2000. He has been involved in infectious diseases research for the past twenty four years and has published over 90 articles in peer-reviewed scientific journals. He has also supervised several students for their masters and doctorate degree programmes. Prof. Jaoko has a keen interest in biomedical research ethics and is a member of the Pharmacy and Poisons Board, the national regulatory authority for the Government of Kenya. He has also been involved in training members of ethics review committees in Kenya in various aspects of research and bioethics, under a collaborative initiative between Kenya AIDS Vaccine Initiative and the Kenya National Council for Science and Technology, with financial support through a grant from the Canadian Global Health Research Initiative.

∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞

ARESA SHORT COURSES

Module 1 of the ARESA Postgraduate Diploma in Health Research Ethics will be held on 17- 28 February 2014 and serves as an introduction to health research ethics. The module is presented as part of the PG Dip but also as a short course. Similarly modules 2 and 3 will be offered as short courses. Some of the topics that will be discussed include:

Module 1: Week 1 (17 – 21 February 2013)

- historical perspectives on the ethics of biomedical & behavioural research
- ethical challenges in human participant research
- international and domestic codes & guidelines
- operational challenges of research ethics committees
- assessing risks and benefits in research
- the ethics of recruitment

Module 1: Week 2 (24 – 28 February 2013)

- the philosophical approach to ethics
- major ethical theories and principles
- African philosophy and research
- legal aspects of health research
- Mock REC meetings

If you are interested in applying for these short courses please forward your curriculum vitae and a short motivation letter outlining your interest. Please indicate if you would like to do week 1, week 2 or both weeks.

Cost:
R3500 per week

All short course applications must be submitted by 17 January 2014.

Contact: Kelsey February at kelseyf@sun.ac.za

∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞

HIGHLIGHTS FROM THE 2nd ANNUAL ARESA RESEARCH ETHICS SEMINAR

19 & 20 September 2013

120 delegates attended this annual seminar from various South African institutions as well as from Kenya, Ethiopia, Uganda, Malawi, Zambia and Nigeria. A wide range of stimulating talks was delivered by South African speakers (Prof Marc Blockman, Dr Theresa Rossouw , Prof Anne Pope, Prof Marc Cotton). International speakers hailed from the University of North Carolina (Prof Eric Jeungst and Prof Stuart Rennie) and University of Ibadan, Nigeria (Michael Igbe). Prof Keymanthri Moodley, Dr Lesley Henley, Dr Malcolm de Roubaix and Dr Lyn Horn contributed to lively panel discussions along with some of the other speakers. On day 1 of the seminar, session 1 focused on HIV Cure research with presentations on the science, the ethics and the new WHO guidelines. Session 2 comprised of three papers given by 2013 ARESA trainees on early phase studies; this was work completed as part of the ARESA 2013 programme. On Day 2 biobanking in Africa was discussed and debated with Prof Eric Juengst (UNC) providing the ethical overview, Prof Akin Abayomi (Stellenbosch University) discussing the scientific issues, Mr Michael Igbe (University of Ibadan, Nigeria) giving an overview of the views of lay people in Nigeria and Dr Ciara Staunton (Stellenbosch University) discussing the challenges to biobank governance. Day 2 and the seminar ended with a discussion of research related injuries by Prof Marc Blockman (UCT) and Prof Anne Pope (UCT) with the recent judgment in the *Venter v Roche Products* case the focus of discussion.

In the interests of space only some of the presentations are summarised below:

New WHO guidelines: ethical implications for prevention and treatment

Dr Theresa Rossouw

The WHO released new consolidated guidelines in June 2013 on the use of antiretroviral drugs (ART) for the treatment and prevention of HIV infection. These guidelines emphasize early initiation of ART at CD4 counts below 500 cells/mm^3, mostly for public health reasons such as reduction of vertical transmission. Definitive data on the advantages of early initiation of ART for the individual are not yet available. Implementation of these guidelines will mean that an additional 26 million people (on top of the 9.7 million already on ART) become eligible for ART and will add 10% to the estimated $23 billion budget for treating HIV/AIDS in developing

countries. These guidelines need to be implemented in an environment of poorly functioning ART programmes and severe budget cuts, such as the $220 million cut to the global AIDS programme announced by the Obama government in 2013. In human terms, this cut represents 640,000 people who could have been treated with ART for one year. In South Africa, lack of funding has already forced the closure of ART clinics run by NGOs, such as the Sinik'ithemba clinic at McCord's Hospital, leaving 5000 patients on ART destitute. The new guidelines also raise questions about extending treatment to patients with high CD4 counts when global coverage for patients with low CD4 counts (<350 cells/mm^3). is only 54% for adults and a dismal 28% for children. Furthermore, a study by the CDC in 2012 revealed that only 25% of HIV-infected patients in the USA have undetectable HIV viral loads. As such, the new guidelines may be a distraction to correcting the existing gaps in the treatment programme.

Many of the same social and environmental factors that fuel disparities in HIV infection, such as poverty, stigma and poor access to healthcare, also contribute to gaps in treatment and care. A programme that fails to address the social context of disease by focusing exclusively on a medicalised approach is bound to fail to reduce new infections optimally. Social transformation is needed and this can only be achieved by employing a social and political response alongside the biomedical one and by actively engaging civil society and its members. The 'cipublic' has to be put back in 'public health'.

∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞

Exploring the ethics of HIV cure research

Prof Stuart Rennie

Diseases do not just have a biological meaning: they also have a social profile. This is obvious in the case of HIV/AIDS from its early appearance as the 'gay plague'. Although stigma still surrounds HIV/AIDS, its social profile has shifted as antiretroviral therapy has changed its status from an invariable 'death sentence' to a manageable chronic condition. Another major change of the meaning of HIV/AIDS may be on the horizon. Recent clinical developments indicate that a cure for HIV may be possible, and researchers around the world are preparing the groundwork for future studies with human participants. In this talk, I explore some conceptual and ethical challenges surrounding HIV cure research. Cure is conceptually problematic. Two ways of understanding 'cure' can be distinguished. According to the first, which in Western culture harks back to religious tradition, cure means the complete removal of the symptoms of a disease and its symptoms. This 'absolute' conceptual of cure differs from a more modern scientific understanding in which 'cure' means a favorably low probability of disease recurrence. This distinction appears in discussions of HIV cure research when speaking of a *sterilizing* cure (where all HIV is eradicated from the body) or a *functional* cure (undetectable viremia without HIV treatment, no disease progression, no CD4 loss, lack of HIV transmission). Talk about HIV cure relates directly to the ethics of HIV research. One of the challenges will be to have HIV-positive persons agree to join trials without them believing (falsely) they will be cured. Other ethical challenges include: having a favorable risk/benefit ratio when risks in early studies may be high and benefits quite low; ensuring fair access to early HIV cure research and potential early cures; negative effects HIV cure research may have on ongoing treatment and prevention efforts; challenges to managing information (including rumours) in the community – particularly those heavily affected by HIV/AIDS – in relation to such trials.

∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞

Ethical Challenges in International Biobanking and Population Genomics Research

Prof Eric Juengst

There is much excitement in contemporary biomedicine about "shifting the paradigm" of health science and health care to an approach to diagnosis and treatment that is "personalized" to

individual patients through genetic and molecular profiling. If fine-grained clinical correlations can be established between different genomic variants, drug efficacies, and prognoses, medicine may be able to "tailor" the dosing of drugs better, and develop earlier preventive interventions. To achieve this goal, however, biomedical scientists need to conduct comprehensive studies of genetic variation across human populations, in order to make fine-grained clinical correlations between different variants and prognoses. Such studies, in turn, require the collection and centralized storage of biological samples, and their distribution to scientists all over the world for genetic analyses that may not be predictable at the time of collection.

Earlier efforts to conduct global human genetic diversity surveys aimed at isolated "vulnerable" and "vanishing" populations encountered challenges by indigenous peoples who felt they were being targeted for exploitation without appropriate community engagement, permission, or benefit-sharing. Efforts to avoid those charges of "biopiracy" were implemented in the International Haplotype Map Project of the 2000's, through extensive community engagement and ongoing communication with the specific communities from whom biological samples were solicited. Unfortunately, those communities were selected against Euro-American categories of "race," exacerbating perceptions that they "represented" the populations of large continental regions of the world. Again, in cases in which immigrant communities in the U.S. were approached about contributing those samples, leaders in their countries of origin complained of being left voiceless by the process. These complaints have led to the emergence of efforts by national governments and ethnic communities to assert "genomic sovereignty" over biospecimens from their populations, and to impose restrictions on the movement, storage, and sharing of such samples for scientific purposes.

The most recent approach to negotiating these clashing scientific needs and social concerns has been to forego the attempt at a Western-based global genomic survey and simply go the part of the globe which we already know to display the entire range of human genetic diversity --the continent of Africa – and have indigenous scientists conduct the survey themselves. The Human Health and Heredity Africa (H3Africa) Initiative, launched by the UK Welcome Trust and the US NIH, seeks to build scientific capacity in Africa by providing support for African scientists to build their own biorepositories and collect samples from their own populations through locally appropriate processes. But Africa is not a single sovereign state either: in fact, its populations are of scientific interest precisely because of the genetic diversity that results from its deep history of socio-political divisions and internal Diasporas. Already, claims to "genomic sovereignty" by particular African polities are complicating the ambitions of H3Africa to create a pan-African genomic research infrastructure. These complications illuminate critical conceptual and ethical challenges to attempting to govern genetic information as national natural resources, which mirror the problems with patenting genes as scientists' intellectual property.

First, as DeVries and Pepper (2013) point out, the boundaries of human populations of interest to genomic researchers and nation states do not coincide: scientists interested in profiling the signature genomic variations of a particular ethnic group will be able to find expatriate members of that group to recruit without much difficulty, given the mobility of modern populations. Moreover, from the point of view of minority communities within particular nation states, it is not always clear that the state will be a more benign guardian of their interests than international scientific agencies. But most importantly, whether the populations are described in national, ethnic, or community terms, framing genomic research in terms of socially defined groups only reinforces a form of genetic essentialism that genomic science itself eschews and expects to refute.

Moreover, to the extent that a property model for governing genomics research is adopted, as if a population's genes were a natural resource that could be mined by a nation's citizenry like the diamonds in its land, the more attractive it will be

to impose a national duty to help cultivate that resource by participating in state-sponsored genomic research. Already, some have called for the creation of a civic duty to donate biospecimens to genomic research for the good of larger groups (Chadwick and Berg, 2001) To the extent that this view is embraced by nation states; it challenges the commitment to voluntary choice that forms the ethical foundation of modern research with human participants.

A concluding analogy: like genomic variation, human populations experience weather variation. Residents of the Sahara experience a lot of wind and dust, so the Sahara would be a good place to study the human effects of wind and dust. But the same wind blows the same dust to the U.S., and the Kalahari also has wind and dust. So perhaps we should think of our DNA as human dust –the dust of our ancestors- being blown about the globe into pockets of different mixtures, rather than as diamonds, lodged uniquely in place forever until we mine them. Just as it makes no sense to try to nationalize the local weather –even when it creates local wealth– it makes no sense to try to nationalize the global human dust storm of DNA, even when it produces local benefits to share.

References:
Jantina de Vries and Michael Pepper, "Genomic sovereignty and the African promise: mining the African Genome for the benefit of Africa" *Journal of Medical Ethics*, 2013
Ruth Chadwick and Kare Berg, "Solidarity and equity: New ethical frameworks for genetic databases: Nature Reviews Genetics 2(2001): 318-321.

∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞

Payment for treatment of trial-related injuries: terminological difficulties

Prof Anne Pope

Venter v Roche Products (Pty) Ltd ZAWCC Case No 12285/08 [7 May 2013] provides insight into the Western Cape High Court's views on the meaning of the usual information about trial-related injuries that is routinely included in the consent documents. The plaintiff (Venter) argued that a tacit contract existed between Roche SA and himself and, on that basis, Roche was liable to pay compensation as though a claim for damages had been pursued in a South African court.
The High Court pointed out that 'compensation' and 'payment of medical costs' are not synonymous terms, the former having a much wider application than the latter. In the documentation under consideration, the intention of the sponsor's offer as described in the consent document was clear. If a trial-related bodily injury occurred as a result of participation in the trial, then the sponsor's insurer would pay for the necessary treatment to put the participant back in the previous position, if possible. This offer of payment is not a legal obligation but rather is based on a moral obligation, i.e. an ex gratia payment. The use of 'compensation' in the document could not by itself change the scope and meaning of what was offered and accepted by the participant. Venter accepted the risk of harm as described and accepted the offer of payment of costs in event of harm. When one accepts the risk of harm, then there is no claim for damages (compensation) if that harm materialises. In other words, in the absence of the offer to pay for the treatment, no entitlement to such payment exists in law. However, this state of affairs does not preclude further separate litigation based in negligence in a South African court.
The DoH 2006 GCP guidelines take their lead from the ABPI guidelines (UK) in explaining how the claim should be processed and calculated, as well as what to do in the event of a dispute about the amount payable. The consent documentation should explain clearly what the insurance covers, that there is no legal obligation on the company to pay compensation, that clinical malpractice insurance differs from clinical trial insurance, and that separate negligence-based litigation in a South African court is possible.

∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞

Declaration of Helsinki: What's new?

Malcolm de Roubaix

The latest version of the World Medical Association Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects (DOH) - was ratified at the 64th WMA General Assembly held in Fortaleza, Brazil, in October 2013. Note that this version supersedes and replaces the previous version and to quote prior versions other than in historic context is counter-intuitive. It is one of six significant WMA Policy documents intended as guidelines for doctors; others cover torture and other forms of cruel treatment of detainees, hunger strikes, patient rights and child health. DOH nevertheless enjoys quite general, though not universal, authority. Doctors who are members of affiliate organisations are directly bound by the principles laid down by DOH, but all health care workers and researchers are also bound through official acceptance of DOH by individual governments, and promulgation in official regulations and guidelines (e.g., South African Good Clinical Practice Guidelines).

DOH is probably the most important of a range of international guidelines for ethical human research (Table 1).

Table 1: International guidelines for ethical human research

1947 Nuremberg Code (in response to WW11 atrocities)

1948 UN GA Universal Declaration of Human Rights and, to give it legal and moral force...

1966 International Covenant on Civil and Political Rights. Art7 prohibits "*...cruel, inhuman or degrading treatment or...(medical or scientific experimentation) without...free consent...*"

1964 WMA Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects 2014

1979 Belmont Report (in response to Tuskegee)

1982 CIOMS *International Ethical Guidelines for Biomedical Research Involving Human Subjects*

1991 CIOMS *International Guidelines for Ethical Review of Epidemiological Studies*

1993 CIOMS *International Ethical Guidelines for Biomedical Research Involving Human Subjects*.

1995 WHO *Guidelines for Good Clinical Practice for Trials on Pharmaceutical Products*

1996 International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) *Guideline on Good Clinical Practice*

2000 Joint UN Programme on HIV/AIDS UNAIDS Guidance Document *Ethical Considerations in HIV Preventive Vaccine Research* updated 2007 *Ethical Considerations in Biomedical HIV Prevention Trials*

2004 WHO A Practical Guide for Health Researchers

2008 CIOMS *international Ethical Guidelines for Epidemiological Studies*

2009 WHO Casebook on Ethical Issues in International Health Research

2010 Singapore Statement on Research Integrity

2012 Ottawa Statement on the Ethical Design and Conduct of Cluster Randomised Trials

So, what's new? Amongst others, the new DOH prescribes

- more protection for vulnerable groups (17,19&20);
- more protection for participants by including the issue of compensation for the first time (15);
- more precise and specific requirements regarding post-study arrangements (34);
- more quality and transparency in the functioning of research ethics committees (23);
- a more systematic approach to the use of placebos, but no weakening in the ethics of placebo use (33);

As a result of reorganising and restructuring the document with sub headings, readability has been improved.

This quite extensive overhaul commemorates 50 years since the publication of the first full DOH in 1964 (there had been a much shorter interim publication in the 1950s) Full understanding of its ramifications requires careful comparison of the current and preceding versions, quite beyond my purpose. I'll focus on a few significant and perhaps controversial changes:

"11. Medical research should be conducted in a manner that minimises possible harm to the environment." In line with contemporary concerns about environmental protection, the language of this injunction has been strengthened.

"12. Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications." The requirement of appropriate education, training and qualifications in science and ethics is novel. It underlines the central importance of ethics in research, as well as the difference between training and education.

"15. Appropriate compensation and treatment for subjects who are harmed as a result of participating in the research must be ensured." This new requirement reiterates the appropriate CIOMS (Council of International Organisations of Medical Scientists) guideline. This is bound to be controversial, given the recent court ruling in South Africa (Venter v Roche) that denies any legal responsibility of sponsors to compensate participants for research-related harms.

"17. Measures to minimise the risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher." The new wording emphasises an additional responsibility to be pro-active in ongoing risk assessment.

"23. This (ethics) committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence and must be duly qualified." The requirements of transparency in committee reviews, and appropriate qualifications for committee members are novel and serve to promote fair and just evaluation, limitation of power-abuse and improved committee/researcher relations.

"34. At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study..." This requirement has been deleted in the final version; the motivation for this on the face of its inappropriate deletion is not apparent. Informing participants after conclusion of a study where appropriate, may be the only way of showing our respect for vulnerable groups and individuals.

"35. Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject." The previous wording was "clinical research"; this more expansive description is problematic since trial registries are not geared to accommodate *all* human research.

The South African National Health Research Ethics Council and other national research ethics councils in Africa will hopefully reflect on the full implications and application of DOH and advise HRECs and through them, researchers.

∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞∞

What have our 2012 ARESA Trainees been up to in 2013…?

Dr Blanche Pretorius Director: Research Capacity Development NMMU South Campus

As a result of the ARESA 2012 training, Blanche has circulated various articles that were used as learning materials during the PGDip program to her REC. She has distributed the Singapore Statement to the 7 Faculties in her institution. Blanche has been invited to do a CPD presentation on ethics to approximately 120 health professionals. She has also been invited to present at the SASOM (South African Society of Occupational Medicine) Annual Congress. Well done Blanche.

Adri Labuschagne: Medical Research Council

Since graduation from the PGDip program, Adri has been appointed a full member of the Research Ethics Committee of the Medical Research Council. Congratulations Adri!

Dr Tina Malan: Department of Psychiatry, Faculty of Health Sciences, Stellenbosch University.

Tina has been accepted onto the registrar program in Psychiatry at Tygerberg Hospital. She will apply her knowledge on Research Ethics in her new job and plans to explore the field of neuroethics. Good luck Tina!

Advocate Jamwell Maswanganyi: Tshwane University of Technology

Since completion of the PGDip program, Jamwell has registered for an MPhil in Applied Ethics, Centre for Applied Ethics, Stellenbosch University. We wish you luck on this philosophical journey!

Conferences & Events

• **12th World Congress of Bioethics**
25-28 June 2014
Mexico City

• **3rd Annual ARESA Research Ethics Seminar**
18 & 19 September 2014
Cape Town, South Africa

• **PRIM&R Public Responsibility in Medicine & Research Conference: Advancing Ethical Research**
5-7 December 2014
Baltimore, USA

Previous issues of the ARESA Newsletters are available at www.sun.ac.za/aresa

FAREWELL MADIBA

1918-2013