



University of Pretoria

SARETI Newsletter: March 2005



SARETI - the South African Research Ethics Training Initiative is a research ethics training programme funded by a grant from the Fogarty International Center and the US National Institutes of Health (<http://www.fic.nih.gov>) SARETI provides Masters-level training in research ethics and non-degree training for members of African Research Ethics Committees, researchers and other stakeholders. The SARETI curriculum is multidisciplinary, combining skills and resources from the University of KwaZulu-Natal and the University of Pretoria. SARETI provides advanced training in research ethics relevant to the health and research needs of the African continent, and hopes to promote and foster African scholarship in research ethics.

This, our third newsletter, provides an overview of the activities of the end of our second and early phase of our third years of activity, and continues as part of a series of periodic updates and communications about SARETI.

1. SARETI SCHOLARS AND FELLOWS

1.1. CURRENT SCHOLARS AND FELLOWS

Between May and August 2004 we recruited our third group of SARETI Scholars and Fellows. We received 48 applications from 13 African countries, as well as applications from Iran and the Philippines. Our 2005 group comprises 3 women and 4 men. Selection was merit based.

- Of these, we accepted one MPhil SARETI Scholar (from Malawi), one MPH Scholar (from Ethiopia), and one MSocSc Scholar (from Zambia).
- Our 2005 Scholars are:
 - Mr Bornwell Sikateyo (Zambia)
 - Dr Firew Mekonnen Wubiee (Ethiopia)
 - Ms Janelisa Musaya (Malawi)
- We also accepted four non-degree SARETI Fellows (two from Nigeria, one from South Africa, and one from Uganda).
- Our 2005 Fellows are:
 - Dr Elizabeth Kwagala (Uganda)
 - Dr David Irabor (Nigeria)
 - Dr Benjamin Olley (Nigeria)
 - Ms Matsie Ratsaka-Mothokoa (South Africa)

South African Research Ethics Training Initiative SARETI

<http://shsph.up.ac.za/sareti.htm>

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1.2. PAST SCHOLARS AND FELLOWS

SARETI Scholars and Fellows on return home have been active in improving health review systems in their home countries. To date:

- Our four SARETI Scholars attended the June 2004 summer programme in international health research ethics at the Bloomberg School of Public Health, Johns Hopkins University, and attended the Kennedy Institute of Ethics Intensive Bioethics Programme.
- The 2004 SARETI MPH students attended a 2-day "Ethics Roundtable" at the Wellcome Trust funded Africa Centre For Health and Population Studies, Mtubatuba, at the invitation of Dr Mike Bennish. This regular event, of which Dr Wassenaar is a co-facilitator, focuses on research protocols and their ethical implications of a rural health research centre.
- Of the 2003 Masters (MPH) Scholars, Ms Joyce Ikingura (Tanzania) has submitted the final version of her research thesis for supervision prior to examination. Ms Ikingura has completed and passed all other components of the MPH. Mr Owen Mapfumo plans to have his thesis submitted by June 2005, delayed because of adverse circumstances in Zimbabwe.
- Of the 2004 Masters (MPH) Scholars, Drs O Manafa (Nigeria) and A Nyika (Zimbabwe) have submitted final drafts of their research theses for supervision prior to final examination. Ms Rose Musesengwa (Zimbabwe) has received ethics approval and is about to commence data collection, and Ms A Keita (Mali) has commenced data collection but is continuing some coursework in 2005 after changing to an MPhil from the MPH.
- All three 2004 SARETI Fellows (Dr M Limo, Dr W Oyibo & Dr H Diallo) successfully completed all their SARETI coursework modules and remain in regular contact and have either continued to serve on RECs, or work in an ethics advisory capacity, or activated research ethics training activities in their home countries (Kenya, Nigeria and Burkina-Faso, respectively). We are in regular contact with these Fellows and those of 2003. Dr Diallo is working on two papers with SARETI staff.
- Collaborative writing projects between Fellows, Scholars and faculty are ongoing.
- We remain in regular contact with the 2003 Fellows, two of whom were accepted for Masters (MPH training) in 2004 (Dr O Manafa and Dr A Nyika).
- On completion of his coursework, Dr A Nyika was awarded a prestigious post-doctoral Fellowship at the Centre for the AIDS Programme of Research in Africa (CAPRISA, funded by NIAID, NIH & DHHS) at UKZN where he is working with Dr Salim Abdool-Karim and Dr J Singh and the CAPRISA ethics team.
- One SARETI Scholar (Dr O Manafa) was nominated on merit to attend the 5th Global Bioethics Forum in Paris, partially funded by SARETI and partially funded by the organisers of the Forum (with kind assistance of Dr F Hirsch).
- On completion of her coursework, Dr O Manafa has been appointed to assist WHO/TDR in Geneva (with Dr J Karbwang) in a research ethics capacity.
- Ms J Ikingura (MPH, 2003) has continued to assist the Tanzanian national REC as its general secretary, and attended an NIH advanced research ethics workshop in Zanzibar in December 2004. Her research thesis will be ready for examination in April 2005.
- Mr Paul Ndebele (SARETI PhD candidate) has successfully defended his PhD proposal and is now a fully registered PhD candidate in the School of Psychology, UKZN. He continues to serve the Johns Hopkins Bioethics programme in an advisory capacity.
- The 2005 Masters students have commenced their SARETI coursework. An introductory basic skills workshop was run for these students by Drs Wassenaar and Mkhize, which was positively evaluated by the new students.
- Four 2005 SARETI non-degree Fellows have been selected and are due to commence their coursework in May 2005. One Fellow declined his place due to a serious MVA; his place has been filled by another candidate but he will be offered a place in 2006 if he is able to accept it.
- Further ('self-funded') students from other degree courses (MSc Clinical Epidemiology, and MMed Community Health & Nursing) participated in various SARETI modules in 2004.

Masters Scholars 2004-2005

Ms Awa Keita

Ms Keita is currently completing her SARETI coursework and developing her research work. She is due to complete her coursework at the end of May 2005.

Ms Rosemary Musesengwa

Since returning to Zimbabwe after completing her MPH coursework in December 2004, Ms Musesengwa has trained research team members for the University of Zimbabwe and University of San Francisco Collaborative project. She attended an ethics training workshop organized by the Medical School, and facilitated at a research ethics training workshop for scientists from the SADC region. Ms Musesengwa is involved in running the MRCZ, reviewing proposals, monitoring four clinical trials in the field, and assisting in developing a research ethics module for the MMed (Medical Ethics) students at the medical school. She is currently conducting her research project on Perceptions of Benefits of Research by Participants of a Clinical Trial. She attended the EU/University of Bergen/SARETI research ethics training workshop in Durban earlier this year, and has recently returned from attending the 6th Global Bioethics Forum in Malawi where she introduced one of the case discussions and acted as a rapporteur.

Dr Ogenna Manafa

Dr Manafa completed her SARETI Fellowship certificate in 2003 and was subsequently accepted into the SARETI MPH (Health Research Ethics) programme in 2004. She completed and passed all her modules. Her thesis is near completion, and she is expecting to submit by the end of April this year. Dr Manafa reports that the SARETI programme has improved her depth and scope of knowledge in bioethics. Through the experience she gained she was able to establish an Ethics Committee in her home institution in Nigeria. She is currently working for the WHO/TDR in Geneva and attended the 6th Global Bioethics Forum in Malawi where she acted as a rapporteur.

Dr Aceme Nyika

Dr Nyika completed a six-month research ethics Fellowship with SARETI in October 2003. He was then awarded a SARETI scholarship to study for a Master of Public Health (MPH) degree in 2004. He has completed both coursework and research project for the MPH. He is finalizing his MPH thesis entitled "Informed consent: Impact of relationships on decision-making process of women in Harare, Zimbabwe". Currently, he is a research Fellow with the Center for the AIDS Program of Research in South Africa (see www.caprissa.org).

Fellows 2004

Dr Abdoulaye Diallo

Dr Abdoulaye (Hama) Diallo commenced a Fellowship with SARETI in March 2004, at the University of Pretoria. He completed his Fellowship in May 2004. Since then, Dr Diallo has been involved in the following ethics-related activities: 1) he has drafted two workshop proposals for training in health research ethics for IRB members and researchers in Burkina Faso. 2) From November to December 2004, Dr Diallo registered for a course on Clinical Trials and Infectious Diseases at Institute Pasteur of Paris with two modules focused on ethics in Clinical Trials management. 3) He is currently in discussion with a colleague from Institute Pasteur (Paris) and the Head of his research institute to plan an international workshop in ethics that will take place in Bobo-Dioulasso (Burkina Faso). He was requested to draft a communication, and will do a presentation on the current situation of health research ethics in Centre Muraz with an outline of the difficulties met by its IRB since its implementation. 4) Dr Diallo is also currently working on two articles in collaboration with SARETI's Exec: One on the "Current situation of health research ethics in Burkina Faso" and the other on "Health priorities in Africa: Case of Burkina Faso".

Dr Moses Limo

Dr Limo is currently Director, Graduate School, Egerton University, involving 1303 postgraduates in 8 faculties. He is also the Vice-Chairman, Biochemical Society of Kenya. Since his SARETI training, he has continued to teach biotechnology ethics and other aspects of bioethics to undergraduate students and is currently planning a postgraduate bioethics course with colleagues. As a member of Egerton University Research Committee he reviews research and funding proposals ethically and scientifically.

Dr Wellington Oyibo

Dr Oyibo attended the 6th Global Bioethics forum in Malawi and met with SARETI staff. He reports that he is preparing an article for publication. Dr Oyibo is also involved in the Fogarty West African Bioethics Initiative (see <http://www.westafricanbioethics.net/index.html>). He also attended the WHO/TDR/World Bank consultative meeting on biotechnology and ethics (ELSI) in Ibadan, Nigeria in March 2005.

Masters Scholars 2005-2006

Ms Janelisa Musaya

Ms Musaya is a researcher from Malawi and on completion of her SARETI training plans to assist in the FIC Bioethics programme at the University of Malawi with Dr Mfutso-Bhengo. Her research topic is to be confirmed by April 2005. She attended the EU/Bergen/SARETI research ethics workshop in Durban in February 2005.

Mr Bornwell Sikateyo

Mr Sikateyo (from Zambia) was formerly a Fellow of the Johns Hopkins Fogarty Bioethics programme, and has been accepted for a SARETI MSocSc (Research Ethics) Masters programme in 2005. His research topic is to be confirmed by April 2005. He attended the 6th Global Bioethics Forum in Malawi in March 2005.

Dr Firew Wubiee

Dr Firew Mekonnen Wubiee is a medical practitioner and is a lecturer in public health at University of Gondar, Ethiopia. He served as a chair of the Institutional Review Board (IRB) at this university for nearly two years. He reports that apart from his exposure in the ethics committee, there is no formal training in the medical school curriculum in clinical and research ethics. As a result, he began to look for opportunities for ethics training to equip himself with the basis and practical procedures. He states that SARETI has transformed him from a layperson to a reasonable ethics thinker. Dr Wubiee feels that the SARETI teaching method is tailored so that students are given exposure to the university ethics committee and are able to evaluate research proposals. He has found the special programme on conflict management, time management and critical thinking classes with SARETI staff particularly helpful in facilitating his learning.

2. SARETI PROGRAMME ACTIVITIES

- SARETI hosted a Research Ethics Training Workshop sponsored by the European Union and the University of Bergen in Durban, South Africa in February - March 2005. This was attended by 65 delegates from 17 African countries. Presenters included Drs Reidar Lie, Ezekiel Emanuel, David Wendler, Drs Wassenaar and Mkhize and Kruger of SARETI, and several European bioethics experts, including Drs Emilio Mordini and Francois Hirsch. The selection of attendees was based on SARETI training applicants who had not secured full masters scholarships or fellowships. All course logistics and arrangements were coordinated by SARETI, and the course attained high satisfaction ratings by attendees.
- It is clear that SARETI is becoming well known as a provider of medium and long-term research ethics training on the African continent. This is evident from the increasing numbers of events which SARETI faculty are invited to attend, and by the diversity and quality of applications for SARETI funding.
- SARETI has also been nominated as a provider of research ethics training for future staff at the Wellcome Trust funded KEMRI site in Kilifi, Kenya (PI: Dr K Marsh).
- SARETI has been nominated as a provider of research ethics scholarship training for the African Malaria Network (AMANET) (PI: Dr W Kilama).
- SARETI has continued to contribute to research ethics library holdings at the Universities of KZN and Pretoria. Subscriptions have been taken on the *Hastings Center Report* and *IRB*, for use at SARETI Journal Clubs with students.
- With the dedicated and skilled help of our two administrators, Ms D Marais, and Ms N Khan, we have continued to improve and refine SARETI's administration and systems. We now have a well-developed student 'Welcome pack', in addition to other programme resources that assist with student and programme administration.
- We have continued to update and revise our website and resources – see <http://shsph.up.ac.za/sareti.htm>

3. SARETI EXECUTIVE AND LECTURING STAFF

- The SARETI Executive for 2005 is:
- Dr Doug Wassenaar: Principal Investigator
- Professor Mariana Kruger: Co-Principal Investigator (Pta)
- Dr Nhlanhla Mkhize: Deputy Co-Principal Investigator (KZN)
- Dr Theresa Rossouw: Deputy Co-Principal Investigator (Pta)
- Professor Carel IJsselmuiden: Senior Executive Member
- Professor Linda Richter: Consulting Executive Member
- Ms Debbie Marais: Administrator (KZN)
- Ms Nasreen Khan: Administrator (Pta)



Members of the SARETI Executive at work: (L-to-R): Dr Nhlanhla Mkhize, Ms Debbie Marais, Ms Nasreen Khan, Professor Mariana Kruger

- We warmly welcomed Drs Nhlanhla Mkhize (UKZN) and Theresa Rossouw (UP) to the SARETI Executive as from March 2004.
- The SARETI Executive met monthly throughout 2004 and met regularly with the group of Scholars and Fellows.
- SARETI academic staff have contributed papers and presentations in 2004 at several international and national meetings and congresses.
- SARETI staff (IJsselmuiden, Wassenaar & Mkhize) are formally collaborating with an EU funded initiative to develop bioethics capacity in West Africa (NEBRA: PI: Dr Francois Hirsch, of INSERM).
- SARETI staff (Wassenaar, Mkhize) have been appointed as members of the advisory board of a Wellcome Trust funded project to improve community consultation at the Kenyan Medical Research Institute's site in Kilifi (PI: Dr S Molyneux).

- **Dr Nhlanhla Mkhize:**

Dr Mkhize, Deputy (Co-PI, UKZN) chaired a session at the 5th Global Bioethics Forum in Paris. In addition, Dr Mkhize has been involved in the following presentations and activities:

International:

Mkhize, N., Cunningham, C., & Houston, S., & (2004). Ethics in indigenous Health: Panel Presentation and Discussion. 7th World Congress of Bioethics. The University of New South Wales, Sydney, Australia (special invitation).

Mkhize, N. (2004, October). "Indigenous concepts of personhood, health and illness: Implications for IRBs". Paper presented at the PRIM&R (Public Responsibility in Medicine and Research) 2004 Annual IRB Conference. San Diego, CA. (29-30 October, 2004) (Keynote Address).

Mkhize, N. (2004). "Indigenous Selves and Ethical Decision-making: Towards Dialogue between Universalism and Communalism in Ethics". Paper presented at the 7th World Congress of Bioethics, University of New South Wales, Sydney, Australia (9-12 November, 2004).

Lavery, J., MacQueen, K., & Mkhize, N. (2004). Understanding cultural differences in research: Panel Presentation and Discussion. Presented at the PRIM&R (Public Responsibility in Medicine and Research) 2004 Annual Institutional Review Board Conference. San Diego, California.

Local:

Mkhize, N. (2004). Culture and Research - Ethical Concerns. Paper presented at the University of KwaZulu-Natal REC Workshop. Nelson Mandela School of Medicine. (9 September 2004).

Mkhize, N. (2004). Universalism and communalism in Ethics: A dialogue. Paper presented at the First Colloquium on Bioethics Strategic Initiative. University of KwaZulu-Natal (Westville). (17 September 2004).

Mkhize, N. (2004). Community Participation in Research: Some Lessons and Reflections. Presented at the Ethics Training Workshop organized by the Research Ethics Committee of the Nelson Mandela School of Medicine, University of KwaZulu-Natal, Durban [26 November 2004].

Mkhize, N. & Potgieter, C. (2004). Research Ethics. Training workshop conducted on behalf of the Research Division of the Psychological Association of South Africa.

Mkhize, N. (2005). Gender Culture and Masculinity (Discussant). National Stakeholder Workshop on Gender, Culture and Rights, organised by the Human Sciences Research Council in Partnership with the Commission on Gender Equality, Health and the Population Council. Johannesburg. [2 February 2005].

- **Professor Mariana Kruger:**

SARETI supported Dr M Kruger's attendance at the OHRP' workshop *Strategies for protection of Human Research subjects globally* for IRB members held in the US. She presented papers at the 36th SIOF meeting in Oslo and at the *Kidz-n-All* Conference in Cape Town on research ethics and childhood cancer. Dr Kruger completed an MPhil (*cum laude*) in 2004 on the topic of ethics education in medical undergraduate students and the paper was presented at the SA Association for Health Educators, 2005. Dr Kruger has been appointed to the advisory committee of HEARD at UKZN to consult on the ethics of research with children, and continues to serve on the RECs of the University of Pretoria and the SA Medical Research Council. She was invited to attend the EFGCP Annual Conference in Brussels to examine the proposed EU regulation on medicinal products for paediatric use. She currently does both GCP (Good Clinical Practice) and research ethics training for postgraduate medical students and coordinates the undergraduate ethics education at the Faculty of Health Sciences, University of Pretoria. Dr. Kruger is the PI of the following clinical trial: Protocol BI 1100.1413 Open-label study evaluating the resistance profile of single dose Nevirapine when combined with a 4 or 7day course of Combivir compared to single dose Nevirapine for prevention of mother to child transmission (Boehringer Ingelheim).

- **Dr Theresa Rossouw:**

Dr Theresa Rossouw attended a 3-day NIH Workshop for Advanced Ethics Training in Zanzibar in December 2004. She was appointed Clinical Head of ARV (Anti-retroviral) Clinic at Pretoria Academic Hospital as from 1 January 2005. She has also been appointed as an extraordinary member of the Department of Family Medicine at the University of Pretoria. She currently does GCP (Good Clinical Practice) training at Pretoria Academic Hospital and at the Faculty of Health Sciences, University of

Pretoria. Topics include ICH-GCP and SA-GCP, and Informed Consent. Dr Rossouw registered for an MPH degree (Biostatistics and Epidemiology track) at the University of Pretoria in January 2005. She is developing a SARETI module for WEB-CT, and has attended a WEB-CT course sponsored by SARETI. Dr Rossouw is also an extraordinary lecturer in the department of Family Medicine, teaching ethical aspects of HIV/AIDS.

- **Dr Doug Wassenaar:**

Drs Wassenaar, Kruger and Mkhize attended the annual FIC programme directors' meeting in Bethesda MD. Dr Mkhize attended at minimal cost to SARETI as he was already in the US at the invitation of PRIM&R. Dr Wassenaar has been appointed to the advisory committees of NIH/FIC Bioethics training programmes in Malawi (PI: Drs T Tomlinson & J Mfutso-Bengo) and Ibadan, Nigeria (PI: Dr C Ademabowo). He presented papers at international research ethics workshops held in Zanzibar (NIH Dept of Clinical Bioethics), Durban (EU/Bergen/SARETI), and Ibadan (WHO/TDR/World Bank). Dr Wassenaar and Dr IJsselmuiden attended the 6th Global Bioethics Forum in Malawi in March 2005, where Dr Wassenaar presented one of the discussion cases. At least 6 SARETI Fellows and Scholars also attended the Forum - no cost to SARETI. Drs Wassenaar, Rossouw and Ms M Stobie attended a lecture by Dr Norman Daniels (On justice) at the Africa Centre, Mtubatuba. Dr Wassenaar has been appointed as an advisor to the research ethics Committee of the Human Sciences Research Council and has also served a period as interim chair of this committee.

- **Dr Carel IJsselmuiden:**

Dr IJsselmuiden, now a Senior Executive Member, remains in charge of the SARETI module "Ethical Issues in International Collaborative Research", which he taught in August 2004. Dr Rossouw took over coordination of Dr IJsselmuiden's other module entitled "Public Health, Ethics and Human Rights". SARETI co-supported the travel costs of Dr C IJsselmuiden who was a keynote speaker at a West African conference initiated by one of our 2003 SARETI Fellows on the use of plants in traditional medicine.



Dr Doug Wassenaar and Professor Carel IJsselmuiden with SARETI MPH student Dr Ogenna Manafa at the 6th Global Bioethics Forum in Malawi

- **Other SARETI Faculty:**

- Ms Nicola Barsdorf, an MHS graduate of the Hopkins Bioethics programme, has been appointed to coordinate the SARETI module on 'Critical Issues in Informed Consent'.
- SARETI co-sponsored Mr Doug Mansfield to contribute to the final version of the SA MRC guidelines on the use of animals in research, now published (see

<http://www.sahealthinfo.org/ethics/ethicsbook3.pdf>) which will assist him in developing a SARETI module on the use of animals in health research.

- Other collaborating SARETI module staff: Informed Consent and Vulnerable Populations: Mr Doug Mansfield, Dr. Pam McLaren, Ms Cathy Slack, Adv. Ann Strode, Ms Nicola Barsdorf. Ethical Issues in HIV Vaccine Trials: Ms Julie Manegold, Dr Eftyhia Vardas, Ms Cathy Slack. Institutionalizing Ethical Review of Health Research: Profs. Peter Cleaton-Jones, Jacques Snyman. Health Law and Ethics: Prof Pieter Carstens, Ms Kitty Barrett-Grant and Adv. Annalise Nienaber.

Publications by SARETI staff:

- Pillay, A.L., **Wassenaar, D.R.**, & Kramers, A. (2004). Ethical issues in the inpatient management of nonfatal suicidal behaviour in the general hospital setting. *South African Journal of Psychology*, 34(3), 349-362.
- Barsdorf, N., & **Wassenaar, D.R.** (2005). Racial differences in public perceptions of voluntariness of medical research participants. *Social Science & Medicine*, 60, 1087-1098.
- Moore SW, Millar AF, Hadley GP, Ionescu G, **Kruger M**, Poole J, Stones D, Wainwright L, Chitnis M, Wessels G. Hepatocellular carcinoma and liver tumors in South African children: a case for increased prevalence. *Cancer*. 2004 Aug 1;101(3):642-9.
- Rayyan, M., Price, V & **Kruger, M.** Neonatal cholinesterase inhibitor poisoning: Materno-fetal exchange of pesticide. *J. Paediatr. Child Health* (2005) 41, 1–2.
- Slack, C.M., Stobie, M., Milford, C., Lindegger, G.C., **Wassenaar, D.R.**, Strode, A., & **IJsselmuiden, C.B.** (2005). Provision of treatment in HIV vaccine trials: A developing country perspective. *Social Science & Medicine*, 60, 1197-1208.
- Hook, D., **Mkhize, N.J.**, Kiguwa, P., & Collins, A. (Eds.) (2004) *Critical psychology*. Cape Town: UCT Press.
- Slack, C., & **Kruger, M.** (2005). The South African Medical Research Council's: Guidelines on ethics for medical research: General Principles: Implications for HIV preventive vaccine trials in children. *South African Medical Journal*, 95 (4), 269-271.
- Molyneux, C., **Wassenaar, D.**, Peshu, N., & Marsh, K. (2005, accepted). Community voices on the notion and practice of informed consent for biomedical research. *Social Science & Medicine*.
- Drs **Wassenaar, Kruger & IJsselmuiden** contributed to the SA MRC HIV Vaccine Ethics Guidelines, now published (see <http://www.sahealthinfo.org/ethics/ethicsbook5.pdf>)

4. THANKS

- The SARETI Executive thanks the following persons for their active contributions to and support of the SARETI programme:

Professor Kuku Voyi, Head of the School of Health Systems and Public Health, University of Pretoria.

Liz Wolvaardt and Shaun Schoeman at the School of Health Systems and Public Health, University of Pretoria.

Members of the SARETI International Advisory Board for support and contributions on various matters.

The 2004-2005 SARETI EXECUTIVE

We welcome your comments on this newsletter and any other aspect of the SARETI programme. Please direct these to maraisd@ukzn.ac.za