ARESA

ADVANCING RESEARCH ETHICS TRAINING IN SOUTHERN AFRICA

Vol. 2 No 1 **June 2012**

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

Dear REC Members,

As mentioned in our previous newsletter, the Centre for Medical Ethics and Law at Stellenbosch University and the University of North Carolina at Chapel Hill (USA) were awarded a grant from the Fogarty International Center of the National Institutes of Health (NIH) to develop and implement the ARESA (Advancing Research Ethics training in Southern Africa) program. The program consists in annually training a cohort of trainees who complete a Postgraduate Diploma in Health Research Ethics (PGDip). In addition, the ARESA program aims to strengthen research ethics networks in Southern Africa by disseminating its results and activities through this newsletter and other channels.

We are very happy to report that the ARESA program is in full swing. Our first cohort of trainees have completed Modules 1 and 2 of our three module program, and have submitted proposals for their required practicum. Module 2 took place in February 2012 and was devoted to the complex and challenging interrelationships between scientific and ethical review of research.

We look forward to engaging with our trainees again in August, when Module 3 of the ARESA program will take place. The theme of Module 3 will be vulnerable populations, where we will explore the challenges involved with research involving children, prisoners, the elderly, persons with mental disabilities, as well as other research that can increase vulnerabilities of participants, such as genetic or HIV and STI research. We will also be holding the first annual ARESA Research Ethics Seminar in conjunction with Module 3 on 30-31 August 2012. The Seminar will address topical and controversial issues in research ethics and we invite you to join us in Cape Town for this event. For more details, visit our website (www.sun.ac.za/aresa) or email us at aresa@sun.ac.za. Finally we take this opportunity to welcome our new ARESA Co-ordinator, Nicola Barsdorf.

Best wishes,
Stuart Rennie and Keymanthri Moodley

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UNIVERSITEIT STELLENBOSCH UNIVERSITY

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2 NEW ARESA TRAINEES

Two trainees who attended module 1 as a short course decided to convert to the full Diploma. A biosketch for each of the new ARESA trainees follows below:

Ms Adri Labuschagne is the Ethics Officer at the Medical Research Council (MRC) in Cape Town. She has been involved with the administration of the MRC Ethics Committee since 1994. Her functions include compiling the agenda and all logistics. She received a Certificate of Competence from the Wits Faculty of Health Sciences in Research Ethics: Conducting Research Responsibly, after a week-long intensive course in 2011, which whetted her appetite for more training. She has therefore joined the ARESA diploma course to extend and formalise her ethics training. She also has an interest in research integrity issues. Adri is funded by the MRC.

Dr Tina Malan is a medical practitioner working as a Clinical Trial Physician for GVI Oncology since 2008. She manages the Rondebosch Clinical Oncology Research Unit in Cape Town and her functions include amongst others, feasibility assessments of new clinical trials, negotiating clinical trial agreements and budgets, recruitment of participants, managing participants medically while participating in a clinical trial, data and safety management as well as overseeing and training clinical research staff. Throughout the clinical trial process Good Clinical Practice and ethical research is her main priority. She therefore enrolled in the ARESA Postgraduate course to enhance her knowledge in the ethical conduct of clinical research and to present research ethics training to others in and outside GVI Oncology. She is funded by GVI Oncology.

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ARESA Module 2

Module 2 of the ARESA Postgraduate Diploma in Health Research Ethics was held from 13-24 February 2012, and was devoted to the issue of dual (scientific and ethical) review of health-related research. Trainees learned about the relationships between ethics and research design, as well as the ethical challenges raised by the different phases of clinical trials. Cases from both biomedical and behavioral research were presented, analyzed and discussed during the two week session.

Visiting Faculty

Dr Amy Corneli is a Scientist in Behavioural and Social Sciences at FHI 360, and she was guest faculty in Module 2 of the ARESA program. She has a PhD in Health Behaviour and Health Education from the University of North Carolina at Chapel Hill and an MPH in International Health from Emory University. Over the past 15 years, she has led research in multiple countries in Africa, the Middle East, Asia, and North America focusing on HIV prevention, prevention of micronutrient malnutrition, and research ethics, including research on comprehension of informed consent, acceptability of informed assent, and functioning of research ethics committees. She currently serves as the Behavioural Principal Investigator on FEM-PrEP, a phase 3, placebo-controlled, clinical trial of oral Truvada PrEP for HIV prevention in women in sub-Saharan Africa. Dr. Corneli has been involved in IRB capacity building activities in Africa and has published ethics-related research in the Journal of Medical Ethics, AIDS and Behaviour, Journal of the International AIDS Society, and Journal of Empirical Research on Human Research Ethics, and Contemporary Clinical Trials.

A critical analysis of two arguments against incentivised biomedical research

Anton A van Niekerk, Director, Centre for Applied Ethics, Stellenbosch University

In this short article, I critically analyse two arguments that are often raised against the idea of incentivising participation in biomedical research. In pointing out the shortcomings of these two arguments, I do not necessarily argue that there cannot be other legitimate reasons for rejecting the idea of incentivised participation under certain circumstances; I'm only arguing that the two arguments discussed below are not valid.

What is an "incentive" or an "inducement" within the context of clinical research? The following elements of this notion can be distinguished. It first of all refers to some benefit or advantageous good (usually money, though it need not be only money) that is offered to research subjects for participating in a research project. The fact that it is offered, presupposes that the subject has a choice to either accept or reject the offer. It is something external to the research project (Grant & Sugarman 2004: 721), i.e. it is a benefit that is not intrinsically linked to possible benefits that could emerge from the research results.

The first argument often raised against this practice is that incentives will induce people to run unnecessary risks. Risk-taking is, of course, a seemingly inevitable part of life in general. It is necessarily implied by the exercise of human freedom. To take a risk means to do something in view of possible gain or profit (like investing in the stock exchange), but without any guarantee that the effort will be successful. This "lack of success" associated with risk-taking can, in many instances, result in experiencing some form of harm.1 Risk-taking is therefore the active pursuit of gain by means of an action that is deliberately undertaken in the full knowledge that it might be unsuccessful and often harmful; it is the deliberate linkage of promise and uncertainty when embarking on action. In the case of alleged "undue" inducements, the argument is that the kind of risk, i.e. one pertaining to one's health, is different from other risks, and that incentives may induce people, particularly if they are vulnerable, to run greater risks than are necessary for their physical well-being.

This argument is only valid on the assumption that the decision about the nature and size of the risk that a potential research subject takes is entirely dependent on the judgment of the subject herself. However, that is and need not be the case when we are dealing with otherwise ethically justified research. Emanuel (2004, 2005a, 2005b), in particular, has forcefully, and to my mind correctly, argued that research can only be deemed morally appropriate when it has been cleared by an institutional review board (IRB) or a legitimate research ethics committee (REC). These committees have a variety of responsibilities. One of their responsibilities, however, is to assess risk in order to make an informed judgment on the balance of risk and benefits of a research project (cf. article 6 of the Nuremberg Code and article B.16 of the Declaration of Helsinki). The IRB therefore represents the proper place and point in the research process where and when the appropriateness of risk-taking is assessed. Research in which the risk is more than the benefits that could accrue from the research is ethically inappropriate and should never be undertaken. Research that is deemed morally appropriate must therefore, on the basis of expert judgment, be of such a nature that subjects, if properly informed, can participate without an excessive fear of harm, even though no guarantee against any form of harm can ever be supplied. If this argument is accepted – and I think it must be accepted – the alleged moral issue of inducements disappears. People are then justified in participating, whether as a result of incentives or voluntarily.

[1] The possibility of harm is normally associated with taking risks, but is not an essential component thereof. If I buy my wife a present for her birthday and I don't want her to know what it is beforehand, but keep it in my cupboard, I run the risk that she will discover it. Her discovering it can, however, in no persuasive sense be regarded as harm to either her or myself.

A second argument developed against offering incentives to participate in research is the claim that such inducements amount to an exploitation of the poor. "Exploitation can be defined as the act of taking unfair advantage of another party to serve one's own interests" (Wertheimer, Macklin, as quoted by Schroeder: Unpublished). Exploitation, as Schroeder persuasively argues, is not always wrong; all of us are every day taking advantage of other people to serve our own interests (Ibid). Exploitation, however, becomes morally dubious when it is directed against poor and vulnerable people who already have very little, and are deprived of what little they have in order to further enrich those that already have. It is prima facie morally repugnant to exploit the poor. However, it is not clear why the possibility of such exploitation should hinder the provision of incentives. When people are exploited, they receive too little and those that exploit them, receive, as a result, too much. The obvious way of correcting such a state of affairs, is to adjust the level of benefit of the exploited people, i.e. to see that a situation obtains in which the exploited people receive more benefits than they currently do. But if that is the way to alleviate exploitation, it indeed offers a case for incentives, not against it, since the practice of inducements is directed at giving people more than they already have.1

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[1]This argument has also been made by Emanuel 2004 and El Setouhy et al. 2004: 20.

Assessing the effectiveness of RECs in developing countries

Ronell Leech (ARESA 2011 trainee)

Ethics review serves to encourage the ethical conduct of research and research ethics committee (REC) members spend many hours in the review process to protect the rights and safeguard the welfare of research subjects. The effectiveness of RECs depends, in part, on the familiarity of REC members with processes and procedures related to the functioning of a REC (Gillam, Guillemin, Bolitho & Rosenthal 2009). In South Africa, despite the fact that 54% of REC members have received training in research ethics or Good Clinical Practice, the performance of RECs is unclear. A report by Moodley and Myer (2007) indicate that variability in operations, infrastructure and training needs exist amongst RECs in South Africa.

The 2011/2012 group of ARESA trainees was tasked to assess the performance of their respective RECs. By doing self-assessment, RECs can evaluate their performances and demonstrate to their stakeholders the legitimacy of their review mechanisms. Several self-assessment instruments are available; mainly from the United States of America or the United Kingdom. Due to the fact that ARESA trainees are from developing countries, the MERETI (Middle East Research Training Initiative) tool was used to obtain baseline benchmark data for the respective RECs. The MERETI tool is a self-assessment tool developed specifically for RECs in developing countries. The rationale for developing the tool was to appraise the performance of RECs against standards that were drawn primarily from international standards.

In addition to specific shortcomings identified by the MERETI tool, the need for an initial training program (induction/orientation) for new REC members was highlighted by several trainees. According to the research ethics literature, this need is not only experienced by new REC members in Africa. Walsh, McNeil and Breen (2005) indicated that most human research ethics

committees in Australia provide minimal training or education for new members. A study by Klitzman (2007) regarding the views of the process and content of ethical reviews of HIV vaccine trials among members of United States (US) Institutional Review Boards and South African (SA) Research Ethics Committees indicated that in both countries most members thought they needed additional training. Of concern is the finding that 40% of SA members reported being self-taught. According to Klitzman (2007), further research is needed to explore whether members who are self-taught view or approach ethical issues differently than members who have been exposed to formal ethics training.

In European countries and the US, new members of research ethics committees undergo a formal induction program to ensure that ethics committee members are empowered with particular knowledge, skills and abilities beyond an intuitive sense of how to protect human research subjects. Therefore, to ensure fully functioning REC members in SA, it is imperative that new members receive appropriate initial training. These training programs should be easily accessible and not extensively disrupt the normal core duties of the members. The aspects that should receive attention during such training should not only focus on administrative aspects of REC operation, but also on the scientific method; ethical analysis; and the regulatory framework.

As the ARESA program is about strengthening and expanding local and regional African capacity, a group of ARESA trainees has decided to develop an initial training program for new REC members that could contribute to the effectiveness of RECs in African countries.

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The protection of whistleblowers in South Africa, in the context of clinical research improprieties

Jamwell Maswanganyi (ARESA 2011 trainee)

Introduction

This article discusses the protection of whistleblowers for clinical research improprieties in the South African context. I will focus on the protection under the Protected Disclosures Act, as applicable in South Africa, and other legal instruments will only be mentioned in so far as they assist in the topic. The Act protects employees who make protected disclosures, in compliance with the requirements of the Act. Disclosures not in compliance with the Act will therefore not be protected. The Act should be read together with the Constitution of the Republic of South Africa (1996) as well as other relevant legislation. Although the Act is general in the sense that it is not meant to specifically apply in the health research context, the main purpose of this article is to show how these general principles could be applicable in the health research setting. This will also provide an opportunity to examine their adequacy.

What is the ethical basis for protected disclosures?

While there may be many different ethical theories accounting for why employees may blow the whistle for improprieties, the article here focuses on the rights-based approach to whistle-blowing. The concept of right is used here in both a moral and legal sense. The argument will be that it is a person's inherent right where improprieties occur that he or she should blow the whistle. Rights' claims may be based on natural rights, which are considered to be inherent in all humans (Beauchamp, Bowie & Arnold 2009). Some of these rights find expression in legal documents. In the South African context, the Constitution provides for a number of rights. Although the Constitution does not make specific provision for dealing with the protection of whistleblowers, it does have provisions dealing with transparency, openness and accountability, amongst other provisions. It also has provisions dealing with the right to freedom of expression, which includes the right to impart information. The Constitution applies horizontally i.e., to both government and private persons. These provisions will give space for whistleblowers to communicate relevant information to relevant stakeholders, against employers and other private persons.

The horizontal applicability of the Constitution can further clarify issues that are not clear from the Act itself, i.e., whether there is a duty on the part of the whistleblower to disclose. The Act merely states, in the Preamble, that 'every employer and employee has a responsibility to disclose criminal and any other irregular conduct in the workplace[1]'. It is therefore unclear if the word 'responsibility' was intended to create a legal duty on the part of the employee. Because of the limited focus here, it is unnecessary to go into further details, except to conclude that a legal duty might exist where another statute or law creates this duty. The horizontal application of the Constitution, which binds private persons also, might indirectly place an obligation on an employee, who becomes aware that the employer is violating the rights enshrined in the Constitution, to act so as to mitigate the violation. This will, however, also be dependent on the role of the employee at the workplace. Ethically, the duty not to do harm to others could place an obligation on the employee to disclose.

Who can make the protected disclosures in terms of the Act?

The Act applies to employment situations. Only employees (of the organization against whom, or against whose employees, the disclosure is made) can make such disclosures. In many clinical trial units and research centres, research assistants, field workers, study site co-ordinators, junior researchers, data capturers and analysts could be classified as employees. The Act makes a restricted definition of an employee, which specifically excludes an independent contractor (s(1)(ii)). This implies that independent contractors will not necessarily be protected, if the nature of their relationship with the employer falls short of the definition of employee. Research investigators who do not qualify as employees will not be protected. The research participants who discover some improprieties on the part of researchers also cannot be protected if they report to sponsors or Research Ethics Committees (RECs), unless there is an employment relationship.

The definition of 'employee' is also based on other factors such as the number of fixed hours worked, the nature of control over the worker, whether the worker is part of the organization of the 'employer' or not, amongst other factors as prescribed in sections 83A and 200A of the Basic Conditions Of Employment Act, 1997 and Labour Relations Act, 1995, respectively. The presence of any of these factors in a relationship triggers a presumption that the relationship is one of employment, even if the parties have themselves concluded an independent contract. This presumption mainly covers situations where employees earn below a particular threshold. If these presumptions apply, it may be to the

[1]It should be noted that the fact that it is only included in the preamble does not change the fact that such a provision could be used in the interpretation of the whole Act. See Burger (2001), A Guide to Legislative Drafting In South Africa. Johannesburg: Technicon SA: 31.

advantage of researchers or research participants who want to blow the whistle, but are prevented from doing so because of the nature of their contract.

Comparative positions on the scope of coverage

A comparative look at other jurisdictions such as New Zealand reveals broader definitions of 'employee' in whistleblower legislation. For example, the definition of employee in New Zealand's Protected Disclosures Act (2007) specifically includes unpaid volunteers, and independent contractors. This creates and clears space for the protection of workers who might not be traditionally considered employees. Note that while South African whistle-blowing legislation does not cover unpaid volunteers explicitly, a case for inclusion can be made when reading the Act together with other labour legislations like the Basic Conditions Of Employment Act, more especially the latter's provisions dealing with its scope of coverage[1], as well as its employee presumption provisions referred to earlier. In addition, unlike its New Zealand counterpart, SA legislation is not confined to employment in the public sector.

What are some possible dilemmas and their resolution?

(a) *Making disclosures in violation of other laws: protecting confidentiality.*

The disclosure may lead indirectly to the disclosure of a patient's health status. This will then, at face value, be in violation of the National Health Act (NHA, 2003), which prohibits disclosures without written consent of the user. However, the same section in the NHA allows unauthorized disclosures under certain circumstances, for example, where non-disclosure poses a serious threat to public health. The person making the disclosure could then use this as a defence, so as to get protection under the Protected Disclosures Act, given that the latter Act does not protect unlawful disclosures. A balancing of interests before making the disclosure must be made here, to avoid unnecessary disclosures resulting in undue harm to patients. The person making the disclosure may equally escape accusations of having made an unlawful disclosure (in violation of the NHA) by showing that the disclosure was made in the interest of the user.

(b) *Making disclosures in violation of other laws prohibiting access to health records.*

Related to the point above, one can imagine a scenario where a disclosure is made by first gaining unauthorized access to health records. For example, section 17(2)(f) of the NHA prohibits the copying of any health record without authority. Whoever does that commits an offence, and risks not being protected under the Protected Disclosures Act.

What type of protection is available to whistleblowers?

The protection is against occupational detriment, which the Act defines as being subjected to disciplinary action, dismissal, harassment, suspension, etc. The other type of protection is one of remedies provided in the event that the employee is a victim of occupational detriment. An employee can claim an automatically unfair dismissal, which entitles him to a higher compensation than ordinary unfair dismissals. An employee can claim up to 24 months (as opposed to 12 months) of the salary the employee was earning at the date of dismissal (Labour Relations Act, 1995). An additional protection is that any other unfair act by employer, short of dismissal, could be classed as unfair labour practice, if related to protected disclosure. Another protection (in the Protected Disclosure Act) relates to the fact that an employee must, on request by the employee, be transferred to another post, or even to another organ of state in case the employer is an organ of state.

[1] S3 of the Basic Conditions of Employment Act (BCEA) does not specifically exclude unpaid volunteers, except those working for an organization serving a charitable purpose. This implies that volunteers in other organizations may be covered by the BCEA.

Is the protection adequate?

The adequacy or otherwise of the protections is linked to the scope of coverage of the Act. As earlier indicated, the Act covers only employer-employee relationships. There is therefore no protection for non-employees. This in turn means that non-employee researchers will not be protected. The same applies to research participants who blow the whistle, who more often than not will not be employees. In the context of medical research, what happens if, in the process of clinical research, it transpires that the patients are involved in drug dealing? Because of the absence of employer-employee relationship, there might be no protection under the Act.

The Act might also not be helpful to vulnerable whistleblowers. For example, vulnerable research participants who lack resources might find it difficult to know when and where to report improprieties. Even after reporting, such participants might be hard hit, as they might not have enough resources to challenge powerful research institutions once victimized. As for other participants like children, the capacity to blow the whistle might also be limited (even if the Act were to cover them, in the event it applies outside employment relationships). The current protection framework is inadequate in research contexts, more especially from the point of view of vulnerable participants.

Other shortcomings of the Act

While Act stipulates that disclosures be made in good faith, there are no clear remedies in case of malicious disclosures. An employer may suffer unnecessary losses from such disclosures. There is also no express provision for immunity from delictual and criminal liability for the disclosure, and this may deter potential whistleblowers.

Conclusion

The discussion above shows that the Act does in fact apply to clinical research situations. The Act, though useful, is limited in its scope, in that it only applies to disclosures made in the context of employment relationships, and some of the relationships involving clinical research do not take place in that context. The protection it affords to whistleblowers in this context is therefore inadequate. The broadening of the scope of the Act, through amendments, is therefore necessary. Such amendments should also accommodate the special social position of vulnerable research participants. In the absence of such legislation RECs and the NHREC have a complaints procedure that can be accessed by researchers and participants where whistle blowing is indicated in research.

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National Health Research Ethics Council (NHREC) Annual Meeting with REC Chairs (May 3, 2012)

On the 3 May 2012 the NHREC held its annual meeting with chairs/representatives of the 33 RECs currently registered with the Council at the Department of Health in Pretoria, South Africa. For the first time, chairs of animal RECs were also invited. In total, 65 REC chairs/members attended this meeting. The meeting was chaired by Thabo Molebatsi, Deputy Director of Health Research and secretariat to the NHREC. The meeting focused predominantly on the recent audit of

RECs that was conducted and the recent proclamation of section 71 (chapter 9) of the National Health Act.

REC Audit Feedback

In terms of the National Health Act No 161 of 2003, the auditing of South African RECs registered with the NHREC is one of the mandates of the NHREC. To fulfil this mandate the Department of Health set the audit process in motion and invited audit companies to attend a briefing session in 2011. Approximately 15 audit companies attended the briefing session and four of the 15 companies submitted formal applications to conduct the audit. The Health Research directorate established a committee to assess the applications and a company/audit service provider was selected based both on its ability to conduct the audit as well as the company structure. The REC audit service provider – Devnomics - was appointed in December 2011 by the Department of Health. Auditors were briefed on the expectations of the NHREC. Criteria against which RECs were to be audited were established by the Audit and Registration Working Group of the NHREC. The audit process was piloted at Pharmaethics – a private REC. Audit fieldwork began on 7 February 2012. All 33 registered RECs have been audited and data collection was completed on 30 March 2012. The final audit report is awaited. Individual audit reports will be sent to individual RECs for feedback and a composite report of the audit will be compiled as well. Based on findings of individual audits, RECs would be required to address specific performance areas and develop a quality improvement program.

Section 71 of the National Health Act

Section 71 of the National Health Act was proclaimed with effect on 1 March 2012. This section has introduced the following requirements for health research:

1. Mandatory written consent
2. Paediatric research: mandatory parental consent
3. Paediatric research: mandatory consent from the Minister of Health for all 'non-therapeutic' research
4. Paediatric research: "therapeutic research" must be in the best interests of the child

Many of these issues have been controversial since the draft legislation was first published in chapter 9 of the National Health Act in 2005. In general section 71 does not address the broad range of health research conducted in South Africa including qualitative research and medical record reviews. It tends to focus on clinical trial research to a large extent. Some of the new regulations appear not to take into account the fact that different research projects carry different levels of risk and hence different levels of protection of research participants may be necessary. Mandatory written consent as a requirement is inconsistent with waivers of consent that may be necessary under specific circumstances (Department of Health Guideline 2004 sections 2.6; 5.9; 7.5; 8.5 and 9.4). There are also other circumstances under which written consent needs to be waived such as in qualitative research interviews with drug gang members where confidentiality breaches may result in criminal prosecution. Mandatory parental or legal guardian consent for paediatric research is at odds with other guidelines where older adolescents may consent independently to minimal risk research such as interviews with female adolescents about perceived barriers to contraceptive use. Parental or legal guardian consent will also preclude research with orphans and vulnerable children. Mandatory ministerial consent for all 'non-therapeutic' paediatric research will affect such research regardless of risk. RECs will not even be able to approve low risk protocols without ministerial "consent". This requirement will place a huge administrative burden on the Ministry of Health and may result in long delays in approval of paediatric research.

When these regulations were first published for comment in 2007, NHREC established a working group – chaired by Cathy Slack - and began work on revisions. The Legal Unit of the Department of Health was included in this working group. The draft revision was completed and approved by

NHREC in 2009, discussed with the Legal Unit in 2010 and submitted to the Legal Unit in Feb 2011. Section 71 was proclaimed without changes in March 2012. NHREC is meeting with the Minister to discuss the matter further. Feedback will be sent to RECs soon after this meeting.

(Report based on a presentation by Cathy Slack)

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Upcoming Conferences & Events

ARESA SHORT COURSES

ARESA SHORT COURSE III: Research and vulnerability (21 to 31 August 2012)

Module 3 will focus on the concept of vulnerability that has, for understandable reasons, become an important concept in regulations and ethical discussions in regard to the ethics of conducting research with human participants in developing countries. The goals of this module are to better understand what is meant by 'vulnerability' and how the various kinds of vulnerability should be taken into account in evaluating the ethics of research studies. Attention will be devoted to vulnerability connected to special populations, such as research with children and mental health research, as well as vulnerability related to research on specific health conditions such as genetic and oncology research. Since the concept of vulnerability is applicable at individual and community levels, attention will also be devoted to ethical issues regarding infectious disease control and associated principles of public health ethics.

The deadline for short course applications for this module is **29 June 2012.**

For more information please contact aresa@sun.ac.za or visit www.sun.ac.za/aresa

ARESA Annual Seminar

30 – 31 August 2012
Newlands Sun, Cape Town, South Africa

Day 1

- Ownership of **biological samples**: a conceptual analysis
- Use, storage & export of biological samples in research
- **Genetic research** – the ethics of community engagement
- Ethical review & governance of genomic resources

Day 2

- **HIV Preventive Research :**
- Treatment as prevention
- Male circumcision & HIV prevention in Malawi
- Ethical complexities and HIV research
- **Scientific Integrity**

For more information contact kelseyf@sun.ac.za

Thinking Ahead: Bioethics and the Future, and the Future of Bioethics
11th World Congress of Bioethics
Rotterdam, The Netherlands (June 26-29, 2012)
http://bioethicsrotterdam.com/

8th International Conference on Bioethics Education: methods, content, trends
Tiberias, Israel (Sept 2-5, 2012)
http://www.isas.co.il/bioethics2012/tiberias.php