

# Education and Training

## Advancing Research Ethics Training in Southern Africa (ARESA)

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Southern Africa is a research-rich environment in which research ethics review is critical. The research ethics review system is well established but considerable variability in capacity and training exists among the various research ethics committees (RECs) in the region. The ARESA programme comprises a Postgraduate Diploma in Health Research Ethics, an annual seminar, a newsletter and an association of REC members. The programme has been developed to promote health in the region via capacity development in the field of research ethics.

Southern Africa is regarded as fertile ground for a wide range of research endeavours because of the enormous burden of infectious disease in the region, highly skilled yet poorly paid medical researchers, a modest ethics review infrastructure and large numbers of treatment-naïve patients.<sup>1,2</sup> South Africa is positioned at the epicentre of the HIV pandemic and HIV research is flourishing scientifically but often floundering from an ethics perspective. Since 1997, the controversial HIV vertical transmission trials have raised questions about standards of care and placebo use.<sup>3,4</sup> HIV vaccine research raised a host of new ethical questions such as the clade of HIV that should be tested in southern Africa, educational thresholds of participants in high-risk phase 1 trials, stigmatisation of participants, and risk-benefit ratios of trials on candidate vaccines, inter alia.<sup>5-7</sup> Microbicide research has experienced major scientific and ethical setbacks,<sup>8-13</sup> and the Orange Farm study on circumcision and HIV prevention (Gauteng, South Africa), in particular, raised major ethical concerns and resulted in *The Lancet* declining publication of results.<sup>14,15</sup> Most recently, the release of results on patients co-infected with tuberculosis and HIV – the SAPIT trial – sparked an international bioethics debate on the vulnerability of research participants, clinical equipoise and the quality of research ethics review in South Africa.<sup>16</sup> The editorial referring to the SAPIT trials in the Hastings Centre Report (April 2010) was entitled ‘The study that should not have been done’ – a damning indictment of HIV/TB researchers in South Africa and the local research ethics committee (REC) that approved the study.<sup>17</sup> Apart from HIV research, TB studies also raise ethical concerns in southern Africa. Large community-based studies using community randomisation methods are scientifically challenging. Home-based research raises questions about privacy and confidentiality, as well as issues related to field worker safety. Community stigmatisation is another important but often neglected social risk.

In addition to infectious disease research, a wide range of other chronic diseases (asthma, hypertension, diabetes, ischaemic heart

disease) are studied in southern Africa – largely because of the vast populations of treatment-naïve patients in the region. In addition the generally poor availability of care at public hospitals and clinics in the region makes research projects a more attractive option to participants who perceive such projects to offer a higher standard of care even if a placebo arm forms part of the research design.

Given the dramatic rise in research activities involving humans in southern Africa, participant protection and RECs are priorities.<sup>18</sup> The recent update of the Declaration of Helsinki deserves more attention in developed and developing countries alike, especially in respect of post-trial obligations.<sup>19</sup> Global responsibility in establishing a culture of excellence in research ethics review remains vital.<sup>20</sup> In South Africa, the last empirical review of RECs was conducted in 2003. Survey findings indicated that the ethics review system in South Africa is functioning at a reasonable level, but there is wide variation among committees. RECs are geographically distant and function in isolation without opportunity to communicate and share ideas. Among institutional RECs, there was a stark contrast between historically disadvantaged institutions and historically advantaged institutions. Nearly a decade after the democratic elections, REC membership was still dominated by white males. Community representation was inadequate. Domination of RECs by scientists and clinicians was pervasive. The review process was widely variable with delays in review ranging from 10 days to 10 weeks. Procedural and bureaucratic demands appeared to impact on the ability of REC members to engage in debate on important substantive ethics issues like standards of care, informed consent and participant remuneration. Research ethics training and educational needs varied widely across the country.<sup>21</sup> The recent debacle over the SAPIT trial has highlighted the need for more extensive research ethics training in southern Africa.

### ARESA programme vision

The goal of building capacity in research ethics in southern Africa cannot and should not be distinguished from the related goals of improving the health and well-being of populations, combating social injustice, and defending human rights. Over the past decade the interrelatedness of these goals has become increasingly obvious. Background conditions of poverty, gender inequality, discrimination, inadequate sanitation, lack of food security, political and criminal violence and a host of other factors are well-established determinants of poor health. As the history of South Africa has made abundantly

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clear, poor population health is not randomly distributed, but is due in large part to political decisions and socio-economic forces. Both health research and structural interventions are required to improve health conditions, but conducting effective and ethically responsible health research in such circumstances is fraught with challenges. In southern Africa, considerations of social justice and human rights cannot be separated from the endeavour of conducting ethically responsible research or from the important task of reviewing health research from an ethical and regulatory perspective. This ethical vision has informed curriculum development, education, mentorship and network-building activities of the ARESA capacity-building programme.

## The ARESA programme

The central mission of the ARESA programme is to build capacity and enhance expertise in research ethics and bioethics primarily through a comprehensive and locally relevant Postgraduate Diploma in Health Research Ethics targeting experienced researchers, clinicians, academics and REC members from southern Africa. The educational programme consists of a structured array of practical experiences and career-development activities directly relevant to the ethical analysis and review of research involving human participants in resource-constrained settings. The diploma programme consists of three 2-week modules over the course of a year. The first module introduces trainees to the history and major principles of research ethics, philosophical ethics (both western and African), health law and human rights. The second module is devoted to the neglected theme of dual (scientific and ethical) review of research. Trainees are introduced to the basis of research methodology, design and trial phases, and how these elements are inseparably linked to ethical issues in research. Attention is also devoted to scientific integrity and publication ethics. The final module explores the concept of vulnerability by examining the research and public health ethics issues arising from certain research areas (genetics, oncology and infectious disease) and specific study populations (children, mental health patients, geriatric patients).

The postgraduate diploma programme will be reinforced and complemented by supplementary goals: holding an annual research ethics seminar, establishing an association of REC members in southern Africa, developing new research ethics curricula, and disseminating research ethics news and information through the ARESA newsletter. The ARESA Research Ethics Seminar will be held over 2 days annually in Cape Town. The first seminar is scheduled for 30-31 August 2012, and it is anticipated that 120 delegates from the South African research ethics community will attend. A vibrant programme supported by international and national invited speakers will be presented. The development of a Research Ethics Committee Association responds to the need to enhance networking and information exchange among members of RECs in southern Africa. The association will also have an educational function in developing and maintaining a list of research ethics resources and online short training courses. Training on the ARESA programme is limited to 10 trainees per academic year, but some modules are offered as short courses as well. The planned ARESA newsletter will be trainee-driven, and two issues will be circulated electronically each academic year. The ARESA programme is funded by the Fogarty International Center at the US National Institutes of Health and is a collaboration between the University of Stellenbosch and the University of North Carolina at Chapel Hill, USA.

## Conclusion

Research activities in southern Africa threaten to outpace local capacity in research ethics. The new ARESA programme aims to enhance practical skills by exposing trainees to fundamentals of research ethics, REC deliberations and conducting protocol review exercises. An important outcome is the development of a package of research ethics training materials by trainees for their home institutions. The programme hopes to contribute to a culture of ethically responsible research in southern Africa through network development, dissemination of information, public awareness and outreach.

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