

## **International Research Ethics Network for Southern Africa (IRENSA) UCT Bioethics Centre**

In 2000 we received a development grant from the US National Institutes of Health's Fogarty International Center (FIC) to facilitate development of a full grant application. In 2002 we completed and submitted our application to the FIC for a capacity building educational grant and we received a generous grant from the FIC in association with the National Institute of Environmental Health Sciences and the National Institutes of General Medicine. This grant for the period 2003-2006 was a major milestone event for our Centre, for UCT and for South Africa. It was one of the first awards made to a non-US Program Director (Prof S Benatar), in a new era of NIH sponsored capacity building in developing countries. In 2007, following an application for a modified and expanded course the grant was renewed for another 4 years (2007-2010), and carry over funds were used for a major reunion in 2011. The grant award of almost US\$ 1,750,000 provided total funding for the eight-year program. Faculty included staff from the Universities of Cape Town, Stellenbosch, London, Toronto, Yaounde (Cameroon), and Zimbabwe as well as from the Ethics Institute of South Africa. The overall goal of the two-pronged IRENSA programme was to develop sustainable multidisciplinary expertise in international research ethics (and to a lesser extent) bioethics in Southern Africa.

### **IRENSA Diploma Programme**

The many applications that we received over eight years (244) and the 97 mid career professionals we trained confirm that our Diploma program has been a successful program in Africa. The programme comprised the following modules, each of which comprised over 60 hours of student/teacher contact time. These were offered through three two-week periods in a one-year period:

Module 1: Research Ethics: Philosophical, Professional & Legal Perspectives

Module 2: Research on Human Subjects in a Cross-Cultural Context

Module 3: Global health, public health ethics & public health research ethics.

Taught by a multidisciplinary Faculty with national and international reputations in bioethics, this Diploma course was in many ways unique in Africa and is impacting considerably on the ethics of research in Southern Africa, where there has been exponential increase in the volume of clinical research in developing countries and concern about unethical research, especially in relation to HIV/AIDS.<sup>1</sup>

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#### <sup>1</sup> **Research Ethics in the Faculty of Health Sciences**

The UCT Faculty of Health Sciences Human and Animal RECs are responsible for ensuring that research conducted in the Faculty complies with current requirements. These committees function under the auspices of the Dean's office and although they have no direct links to the Bioethics Centre, several of our members have served on them and have made contributions to improvements in their processes, structure and management. Between 1999 and 2010 the annual number of research ethics protocols evaluated by the committee almost doubled from 323 to 603.

During 8 years of the Diploma programme (2003-2010), we trained 97 mid-career professionals, *40 male and 57 female colleagues, of whom 38 were white and 59 black. This distribution met the requirement to include previously disadvantaged and 'minority' groups.* They were recruited from academia (research centers, RECs, Bioethics Centers), Government CABs, the South African Medical Association, the South African Defence Force, South African Vaccine Initiative, South Africa Vaccination and Immunisation Centre, National Institutes for Communicable Diseases, the SA Medical Research Council, Harvard AIDS Institute, Medscheme (one of the country's largest medical insurance companies and health care providers), Anglo-Gold, one of Africa's major mining companies and the National Research Ethics Council.

The background disciplines of our participants included: science, medicine, the social sciences, law, dentistry, military medicine, nursing, pharmacology, religious ministries, anthropology, engineering, sports science, and physiotherapy.

34 of the 97 participants had doctoral degrees.  
58 served on 40 REC's in SA & 8 other African countries  
23 were chairs, deputies, or secretaries of REC's  
28 were head departments, government agencies or other organizations

Elsewhere in Africa IRENSA students serve on 9 RECs at the following institutions in 8 countries: Universities of Addis Ababa (**Ethiopia**), Dar es Salaam (**Tanzania**), **Malawi**, **Zambia**, **Zimbabwe**, Makerere (**Uganda**), the Drug Regulatory Unit of the Ministry of Health (**Botswana**), Department of Research Development (**Kenya**), KEMRI/Wellcome Trust Collaborative Research Program (**Kenya**), the Tropical Pesticide Research Institute (**Tanzania**), and the National Council for Science and Technology (**Uganda**).

### **Annual National Research Ethics Seminars**

Since 2001 annual two-day refresher seminar (conducted within our IRENSA framework) served almost 1000 participants. An important feature of these seminars was our use of IRENSA's top students to present major lectures and case presentations. This has been a valuable method to promote students' careers and skills in research ethics. A serendipitous benefit of this annual program has been the networking opportunity it offered participants.

Our two-pronged program, the one-year IRENSA diploma and the Annual Research Ethics Seminar, has successfully built research ethics capacity in our students, their home institutions, and increasingly in the southern African region. The teaching modules, coupled with a solid practicum that addresses local institutional issues in research, have provided, and will continue to provide, a rich, diverse educational experience for our 97 trainees. We have solid evidence our program was successful and that our cohort of trainees are now playing important and effective roles at their home institutions.

In part due to our activities and those of others interested in research ethics South Africa's public health sector has been reorganized pursuant to laws that have recently become effective. Most notably, RECs have come under increasing government regulation. Under the new law, the Minister of Health appointed an Interim National Health Research Ethics Committee (*Chaired by Solomon R Benatar, IRENSA Program Director*). That Committee published National Health Research Ethics Guidelines. Under the new law the Minister of Health subsequently formed the National Health Research Ethics Council. (This is currently chaired by one of our trainees and several other IRENSA trainees also serve on this committee). One of the Council's tasks has been to issue regulations that will require every REC in the country to become accredited.

One prerequisite of full accreditation is that REC members must be trained in research ethics. It was anticipated some years ago that increasing pressure would force other African countries (where substantial research is done with sponsorship from developed countries) to enact similar regulations. This has indeed been the case, as reported by many of our IRENSA graduates from other countries in southern African (see Final Impact report of IRENSA).

### **Reunion 2011 (IRENSA Classes 2003-2010)**

This two-day reunion, held at the Colleges of Medicine of South Africa was attended by 9 of the 16 Faculty members who had taught at some time in the 8-year cycle, and by 65 of our trainees. Everyone who attended had an opportunity to speak about the impact of IRENSA on their professional lives and their institutions. In response to a previous request many of our trainees had submitted short written descriptions of their progress. Lightly edited versions were included in the IRENSA Impact Document that also includes reflections of some of the Faculty. A copy of this document was sent to the FIC, to each member of Faculty and all trainees on our Diploma program.