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The *Strategic Initiative for Developing Capacity in Ethical Review* (SIDCER) is an independent public-private partnership initiative. SIDCER promotes responsible decision-making within countries and institutions so that research participants and their communities experience a real value from ethical review and its contribution to health research. SIDCER provides the international community with not only a means to build in-country human subject protection programs, but also a way to measure and provide accountability regarding the quality and effectiveness of ethical review worldwide. This is the approach SIDCER set out from the start, and it is the approach SIDCER will remain true to over the next 10 years.

The Beginning

In 2001, SIDCER was launched under the aegis of the UNICEF/UNDP/World Bank/World Health Organization *Special Programme for Research and Training in Tropical Diseases* (WHO/TDR) as a public-private partnership project. SIDCER is designed to address the principal gaps and challenges in ethics encountered in global health research.

Based on the experience of SIDCER over the past 10 years, it was found that differences in the standards and practices of ethical review in different institutions have contributed to inhibiting progress in health research. This is not acceptable, especially from an ethical perspective. Research is needed to prevent or alleviate suffering brought about by disease. Ethics committees do function differently in

different countries and different institutions. No one model that will work for all ethics committees around the world. Nevertheless, ethics committees have an obligation to raise their standards and improve their practices by working more closely with one another and those who carry out the research.

The initiative's network of regional fora creates unique opportunities for professional development and learning, while fostering innovative approaches to cross-cultural, cross-national, and cross-regional understanding and mutual support. These fora span the world, and include **FERCAP** (*Forum for Ethical Review Committees in Asia and Western Pacific Region*) in Asia and Western Pacific, **FLACEIS** (*Fora Latino Americano de Comites de Etica en Investigación en Salud*) in Latin America, **PABIN** (*Pan-African Bioethics Initiative*) in Africa, **FECCIS** (*Forum for Ethics Committees in the Confederation of Independent States*) in Eastern Europe (the former Soviet Union), and **FOCUS** (*Forum for Ethical Review Boards/Institutional Review Boards in Canada and the United States) in North America*).

The Aim

The aim of SIDCER is to ensure global protection for all people participating in health research through partnerships that cross cultures, societies, sectors, and organizations. This vision is expressed in its organizational structure as well as in the activities and guidance it develops and promotes.

The Organization

The organization comprises a steering committee, advisory board, and secretariat. The steering committee is responsible for the program development and funding. Members include representatives from the regional fora and from invited partner organizations.

The initiative's advisory board is composed of representatives of organizations involved in international health research and ethics. Its function is to advise the steering committee on the objectives and development of SIDCER and its projects.

The secretariat provides overall coordination of the activities of SIDCER and helps to promote international and multi-sectoral cooperation with the initiative.

The Mission

SIDCER's overall mission is to foster competent and independent in-country decision-making to promote the responsible conduct of human research through its network of fora and to monitor the quality and effectiveness of ethical review worldwide. Mutual understanding and respect for cultural, regional, and national differences plays a vital part in this process, along with education at all levels, both formal and non-formal.

The Activities

SIDCER supports relevant regional structures and activities, including meetings and workshops to build local capacity for ethical review, strengthening and expanding its international network. The training curriculum on human subject protection and the standards operating procedures (SOP) training workshop for ethics committees have been performed within the regional fora.

To develop ethics in health research within the context of local values, SIDCER takes into account international standards like the WHO/TDR *Operational Guidelines for Ethics Committees that Review Biomedical Research* (2000), as well as national and international ethical and regulatory frameworks linked to ethical review. SIDCER promotes the development of quality assurance and processes for improvement in health research ethics, focusing primarily on ethical review practices in its publication of *Surveying and Evaluating Ethical Review Practices* (2002*)*. SIDCER also promotes sustainable in-country infrastructure for ethical review and provides a systematic approach to surveying and evaluating ethical review practices.

In 2003, SIDCER worked together with the *Western Institutional Review Board* (WIRB) in the establishment of the post-graduate fellowship program on bioethics and ethical review. The aim

of the program is to better understand ethics in different settings and to enhance the capacity of individuals from different countries to develop and apply ethical principles and practices when reviewing health research. The goal has been from the start to develop an enabling environment that promotes shared values and a common understanding of best practices for protecting research subjects. In the past 7 years, the program has trained 62 scientists from the regional fora countries. Most of these fellows now play a pivotal role in promoting ethical health research in their own countries and in shaping the growth of the regional fora.

In 2005, SIDCER launched the *SIDCER Recognition Program* to assess and evaluate the ethical review practices of ethics committees. The five SIDCER standards were established based on the WHO/TDR *Operational Guidelines for Ethics Committees that Review Biomedical Research* (2000) and the *International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Harmonized Tripartite Guideline-Guideline for Good Clinical Practice (GCP)* (1997). The SOPs for the recognition program and the SIDCER surveyors' training curriculum were developed, and the SIDCER surveyors were trained. The three ethics committees that were surveyed during the first year of the program were the *Joint Institutional Review Board* (JIRB) in Taipei, the *Changhua Christian Hospital Institutional Review Board* in Changhua, and the *Royal Thai Army* Medical Department Institutional Review Board in Bangkok. The *SIDCER Recognition Program* SOPs and the surveyors' training curriculum have been revised, taken into account the experiences from the first year surveys. The external evaluation of the recognition programme has been performed after 5 years of its implementation to further improve and maintain the quality of the surveyors' training, surveyors, and the operation of the recognition program.

In 2010, the human subject protection training curriculum was harmonized and the core presentations for the course have been developed.

The Progress

After 10 years of its existence, SIDCER managed to establish local training and capacity strengthening program, competent ethics committees, and ethical review system in 12 countries/areas (Bhutan, China, India, Indonesia, Philippines, Sri Lanka, South Korea, Taiwan, Thailand, Ethiopia, Russia, and Uganda), a total of 76 ethics committees have been recognized as compliance with international standards. These ethics committees have served as national and international benchmarks that define the performance of ethics committees in Asia and Africa. They continue to influence the national research environment towards more defined ethical regulations and infrastructures towards more accountability in the conduct of health research. The process of establishing systems and infrastructure for the ethics committee accreditation is on going in two countries, *i.e.,* Thailand and the Philippines.

The Challenge

Creating sustainable ethical review system in research is a daunting task but it is imperative for quality research. The research stakeholder network is vital for the development and maintaining the quality of the system. In addition, "political will" needs to be fostered not only at the international levels but also nationally, so that health research and human subject protection are placed at the top of the political agenda.

References

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