EDCTP Portfolio

Ethics and Regulatory Strengthening

1 Ethics (IRB and NEC)

Summary table of ethics (Institutional Review Boards (IRBs) and National Ethics Committees (NECs) projects)

Project Acronym (Coordinator)	Type of Project (NEC or IRB)	Project Goal	Hosting Institution	Status
JANKO-VSCR-ETHICS	Support for courses on ethics	Capacity Building	Vienna School of Clinical Research	Completed
ASEFFA-PABIN-ETHICS	Support for courses on ethics	Capacity Building	Armauer Hansen Research Institute (AHRI)	Terminated
SPRUMONT-TREEE-1-ETHICS	Support for courses on ethics	Capacity Building	University of Neuchâtel	Completed
MATSIEGUI-GABON-ETHICS	NEC	Capacity Building	Ministry of Public Health, Republic of Gabon	Completed
TINDANA-NAVRONGO-ETHICS	IRB	Capacity Building	Navrongo Health Research Centre, Ghana Health Service	Completed
BENGO-MALAWI-ETHICS	NEC, IRB	Capacity Building	College of Medicine, University of Malawi	Completed
BENGO (NDEBELE)-MALAWI-ETHICS	NEC, IRB	Capacity Building	College of Medicine, University of Malawi	Completed
FALUSI-IBADAN-ETHICS	IRB	Capacity Building	University of Ibadan	Completed
MANAFA-NIMR-ETHICS	IRB	Capacity Building	Nigerian Institute of Medical Research (NIMR)	Completed
MOODLEY-ERECCA-ETHICS	Support for courses on ethics	Capacity Building	University of Stellenbosch	Completed
KILAMA-AMANET-1-ETHICS	Support for courses on ethics	Capacity Building	African Malaria Network Trust (AMANET)	Completed
SEWANKAMBO-MAKERERE-ETHICS	IRB	Capacity Building	Makerere University College of Health Sciences (MUCHS)	Completed
HOLM-CARDIFF-ETHICS	Support for courses on ethics	Capacity Building	Cardiff University	Completed
MUNYATI-MRCb&c-ETHICS	NEC, IRB	Capacity Building	Medical Research Council of Zimbabwe (MRCZ)	Completed
HOUNGNIHIN-BENIN-ETHICS	NEC	Capacity Building	Ministry of Health (Benin)	Completed

PETROS-ETBIN-1-ETHICS	IRB	Capacity Building	Addis Ababa University	Completed
ADEBAMOWO-WABT-ETHICS	NEC	Capacity Building	West African Bioethics Training Program (WAB), University of Ibadan	Completed
WANE (KAYITENKORE)-RWANDA-ETHICS	NEC	Capacity Building	Rwanda National Ethics Committee, Ministry of Health	Completed
CHANGALUCHA-NIMR-ETHICS	IRB	Capacity Building	National Institute for Medical Research (NIMR)	Completed
CHILENGI (KILAMA)-AMANET-2-ETHICS	Support for courses on ethics	Capacity Building	Africa Malaria Network Trust (AMANET)	Completed
MASSAGA (MASHALLA)-TANHER-ETHICS	NEC	Capacity Building	Tanzania Health Research Forum, National Institute for Medical Research	Completed
ONAPA-UNCST-ETHICS	NEC	Capacity Building	Uganda National Council for Science and Technology (UNCST)	Completed
MASON-BRTI-ETHICS	IRB	Capacity Building	Biomedical Research and Training Institute (BRTI)	Completed
KHULUMANI (KASULE)-BOTSWANA-ETHICS	NEC, IRB	Capacity Building	Health Research Unit, Ministry of Health Botswana	Ongoing
MUPENDA-CIBAF-MZADI-ETHICS	IRB	Capacity Building	Centre Interdisciplinaire de Bioéthique pour l'Afrique Francophone (CIBAF)	Completed
OKITOLONDA-CIBAF-PALABRE-ETHICS	NEC	Capacity Building	Centre Interdisciplinaire de Bioethique pour l'Afrique Francophone (CIBAF), Kinshasa School of Public Health	Completed
BOATENG-NMIMR-ETHICS	NEC, IRB	Capacity Building	Noguchi Memorial Institute for Medical Research, College of Health Sciences, University of Ghana	Completed
WASUNNA-KEMRI-ETHICS	IRB	Capacity Building	Kenya Medical Research Institute (KEMRI)	Ongoing
FUMANE-MOZAMBIQUE-ETHICS	NEC, IRB	Capacity Building	Ministry of Health, National Health Institute, Comité Nacional de Bioética para Saúde (CNBS)	Completed
UKPONG-NHVMS-ETHICS	Support for courses on ethics	Capacity Building	New HIV Vaccine and Microbicide Advocacy Society (NHVMAS)	Completed
SARR-CNRS-ETHICS	NEC	Capacity Building	Senegal National Health Research Council (Conseil National pour la Recherche en Sante -CNRS)	Completed
WASSENAAR-	Support for courses	Capacity Building	University of KwaZulu-Natal	Ongoing

SARECCER-ETHICS	on ethics			
IJSSELMUIDEN-MARC-ETHICS	Coordination function	Capacity Building	Council on Health Research for Development (COHRED)	Completed
MBIDDE-UVRI-ETHICS	IRB	Capacity Building	Uganda Virus Research Institute (UVRI)	Completed
SPRUMONT-TREEE-2-ETHICS	Support for courses on ethics	Capacity Building	Institute of Health Law, University of Neuchâtel	Completed
MATSIEGUI-CAEN-ETHICS	NEC	Capacity Building	Comité National d'Éthique pour la Recherche du Gabon	Ongoing
KOLLIE-LIBERIA-ETHICS	IRB	Capacity Building	University of Liberia-Pacific Institute for Research and Evaluation Africa Center (PIRE)	Completed
RULISA-KUTH-ETHICS	IRB	Capacity Building	Kigali University Teaching Hospital (KUTH)	Completed
MUGYENYI-JCRC-ETHICS	IRB	Capacity Building	Joint Clinical Research Centre (JCRC)	Completed
GAIE (NDEBELE)-BOTSWANA-ETHICS	IRB	Capacity Building	University of Botswana	Ongoing
KAPTUE-CNEC-ETHICS	NEC	Capacity Building	Cameroon National Ethics Committee (CNEC)	Ongoing
WOLDEAMANUEL (PETROS)-ETBIN-2-ETHICS	NEC, IRB	Capacity Building	Ethiopian Bioethics Initiative (ETBIN), Addis Ababa University	Ongoing
YEVOO-GHANA-ETHICS	IRB	Capacity Building	Dodowa Health Research Centre (DHRC)	Ongoing
BHATT-KENYA-ETHICS	NEC	Capacity Building	University of Nairobi	Completed
BUKUSI-KENYA-ETHICS	IRB	Capacity Building	Kenya Medical Research Institute (KEMRI)	Ongoing
OTIENO-KENYA-ETHICS	IRB	Capacity Building	Centre for Research and Technology Development (RESTECH)	Ongoing
MANDA-MALAWI-ETHICS	IRB	Capacity Building	College of Medicine, University of Malawi	Ongoing
OTUONYE-NIMR-ETHICS	IRB	Capacity Building	Nigerian Institute of Medical Research (NIMR)	Ongoing
OYEDEJI-NIMR-ETHICS	IRB	Capacity Building	Nigerian Institute of Medical Research (NIMR)	Ongoing
KRUGER-SAREN-ETHICS	Coordination function	Capacity Building	University of Stellenbosch	Ongoing

MSAMBICHAKA-TANZANIA-ETHICS	IRB	Capacity Building	Ifakara Health Institute	Ongoing
TEMU-LZIRB-ETHICS	IRB	Capacity Building	National Institute for Medical Research (NIMR)	Ongoing
BIRUNGI-TASO-ETHICS	IRB	Capacity Building	The AIDS Support Organization (TASO)	Ongoing
ZIMBA-ZIMBABWE-ETHICS	IRB	Capacity Building	Harare City Health Department	Completed
OUEDRAOGO-BURKINA FASO-ETHICS	IRB	Capacity Building	Centre Muraz Research Institute	Ongoing
TANGWA-CAMBIN-ETHICS	Coordination function	Capacity Building	Cameroon Bioethics Initiative (CAMBIN)	Ongoing
OSEI-ATWENEBOANA-CSIR-ETHICS	IRB	Capacity Building	Council for Scientific and Industrial Research (CSIR)	Ongoing
DAMASCENO-MOZAMBIQUE-ETHICS	IRB	Capacity Building	Eduardo Mondlane University and Maputo Central Hospital	Ongoing
NTSIBA-CERSSA-ETHICS	IRB	Capacity Building	Comité d'Ethique de la Recherche en Sciences de la Santé (CERSSA) [Congolese Ethics Committee]	Ongoing
NOOR-AAPH-ETHICS	IRB	Capacity Building	Africa Academy for Public Health (AAPH)	Ongoing
OKULLO-MAKERERE-ETHICS	IRB	Capacity Building	Makerere University College of Health Sciences (MakCHS)	Ongoing
OLUPOT-OLUPOT-MRHIRC-ETHICS	IRB	Capacity Building	Mbale Regional Hospital Institutional Review Committee (MRHIRC)	Ongoing
NKANDU-ZAMBIA-ETHICS	IRB	Capacity Building	University of Zambia (UNZA)	Ongoing
MUTENHERWA-BRTI-ETHICS	IRB	Capacity Building	Biomedical Research and Training Institute (BRTI)	Ongoing
OLOO-CREATES-ETHICS	IRB	Capacity Building	Strathmore University, Centre for Research in Therapeutic Sciences (CREATES)	Ongoing
EKOUEVI-TOGO-ETHICS	NEC	Capacity Building	Département d'Epidémiologie et de santé Publique, Faculté Mixte de Médecine et de Pharmacie, Université de Lomé (Togo)	Ongoing
KANGWENDE-ZIMBABWE-ETHICS	IRB	Capacity Building	Africa University	Ongoing
MBAE-ECSA-ETHICS	IRB	Capacity Building	East, Central and Southern Africa – Health Community	Ongoing
MOMBO-NGOMA-	IRB	Capacity Building	Medical Research Unit – Institutional Review Board	Ongoing

MRU-ETHICS			(MRU-IRB), Albert Schweitzer Hospital	
NYIKA-ZIMFRI-ETHICS	Coordination function	Capacity Building	Public Health Projects in Africa (PHPAfrica)	Ongoing
OKOYE-AGCPN-ETHICS	Support for courses on ethics	Capacity Building	Association for Good Clinical Practice in Nigeria (AGCPN)	Ongoing
SOW-CNERS-ETHICS	NEC	Capacity Building	Guinean National Ethic Committee for Health Research (CNERS)	Ongoing
ATASHILI-BUEA-ETHICS	IRB	Capacity Building	University of Buea	Ongoing
TOUKO (PEYOU NDI)-OCEAC-ETHICS	IRB, NEC	Capacity Building	OCEAC: Organisation de Coordination pour la lute contre les Endémies en Afrique Centrale (Organization for the Coordination of Endemic Disease Control in Central Africa)	Ongoing

1.1.1 Janko-VSCR–Ethics

EDCTP Project Coordinator:	Christa Janko (Vienna School of Clinical Research, Austria)
EDCTP Call Title:	Support for Courses and Seminars on Ethics
EDCTP Project Title:	Training on Ethical Aspects of Clinical Research for Members of African National Ethics Committees and for African physicians and investigators
EDCTP Project Code:	CB.2005.41300.008
EDCTP Project Start Date:	1 December 2006
EDCTP Project End Date:	30 November 2008
Collaborators:	• Michel Anoumou Missinou (Gabon)
Type of Project:	Support for courses on ethics
Goal:	The aim of the training on ethical aspects in clinical research is to help African clinical researchers as well as African National Ethics Committee (NEC) members to understand the basic principles and internationally acknowledged standards, guidelines and regulations of ethics in clinical research.
Objectives:	• Develop an understanding of the principles and basic considerations of ethics in clinical research • Appreciate the roles and the responsibilities of ethics committees as defined by current guidelines and regulations • Understand the unique aspects associated with vulnerable patient populations and specific therapeutic areas • Understand the legal, administrative and organisational aspects associated with ethics in clinical research.
Cofunders:	• Austrian Federal Ministry of Science (Austria) • INDEPTH Network (Ghana)
Status:	Completed
Results and Outcomes:	1. Training (resources developed (e.g. manuals) and human capacity developed) – Trained eight participants in the “Train the Trainer” course and 18 participants in the “Ethical Aspects of Clinical Research” course. 2. Networking/collaborations developed – Medical Research Unit, Albert Schweitzer Hospital Lambarene (MRU) – University of Health Sciences (USS), Libreville – National Centre for Medical Research (CIRMF), Franceville

1.1.2 Aseffa-PABIN–Ethics

EDCTP Project Coordinator:	Abraham Aseffa (Armauer Hansen Research Institute (AHRI), Ethiopia)
EDCTP Call Title:	Support of an African Coordinating Office for Ethics
EDCTP Project Title:	Establishing an African Coordinating Office for Ethics (PABIN – Pan African Bioethics Initiative)
EDCTP Project Code:	CB.2005.41301.001
EDCTP Project Start Date:	15 December 2006
EDCTP Project End Date:	23 September 2008
Collaborators:	• Getachew Aderaye Desta (Ethiopia) • Tsehaynesh Messele (Ethiopia) • Zerihun Tadesse (Ethiopia) • Yemane Teklai (Ethiopia)
Type of Project:	Support for courses on ethics
Goal:	This project intended to strengthen the work of the Pan-African Bioethics Initiative (PABIN) and its Secretariat in promoting the establishment/strengthening of national bioethics initiatives and ethical review committees (ERCs) in Africa.
Objectives:	The main aim of the project was to build capacity in health research ethics in Africa in order to contribute to meeting major African public health needs through strategic research initiatives. The project was to develop research ethics capacity that promotes national capacity for carrying out clinical trials with the support of European and international partners. Specifically, the project was to contribute to creating, as needed, national ethics committees, local ethical review committees, and national systems for ensuring high quality and efficiency in the ethical review of clinical trials and health research generally.
Status:	Completed
Results and Outcomes:	Project was stopped based on EDCTP strategic advisory board (Partnership Board) recommendation in May 2008. The following was achieved: 1. Infrastructure/capacity development – One computer, one photocopy machine and one colour printer were purchased. A part-time coordinator and assistant were employed. 2. Training (resources developed (e.g. manuals) and human capacity developed) – The PABIN Executive Committee meeting was held (18-19 January 2007; 9 participants). PABIN was registered in Lusaka, Zambia. The PABIN Secretariat organised training on SIDCER Recognition Program for the national ethical committee of Ethiopia, the AHRI/ALERT Ethics Committee and the Addis Ababa University Medical Faculty Ethics Committee on Human Subject Protection and Standard Operating Procedures (20-24 November 2006). The follow-up on this is continuing with assistance to the committees in finalising their SOPs and implementation. PABIN secretariat conducted training on research ethics (human subject protection and SOP development) and GCP ethics committee members and researchers in Zanzibar (4-9 February 2008; 16 participants). PABIN Secretariat sponsored six month hands on training in ethics review for three participants at Western Institutional Review Board (WIRB) in Olympia, USA, with financial support from

	WHO/TDR and WIRB. The PABIN secretariat collaborated with AHRI and Norwegian partners to launch FRONTER, an internet-based ethics training of medical professionals (residents) at Addis Ababa University. The training was launched at a workshop in Addis Ababa (27-28 February 2008). The modules were jointly developed by AAU and the University of Oslo. The training involves a period of face-to-face contact/discussions in addition to online interaction with trainers. 3. Networking/collaborations developed – African Malaria Network Trust (AMANET)

1.1.3 Sprumont–TRREE-1-Ethics

EDCTP Project Coordinator:	Dominique Sprumont (Health Law Institute, Switzerland)
EDCTP Call Title:	Support for Courses and Seminars on Ethics
EDCTP Project Title:	Training and Resources in Research Ethics Evaluation for Africa (TRREE for Africa)
EDCTP Project Code:	CB.2005.41300.004
EDCTP Project Start Date:	1 November 2006
EDCTP Project End Date:	1 November 2008
Collaborators:	• Clement Adebamowo (Nigeria) • Charles Becker (Senegal) • Marie-Charlotte Bouësseau (Switzerland) • Ogobara Doumbo (Mali) • Marie Hirtle (Canada) • Wen Kilama (Tanzania) • Dirk Lanzerath (Germany) • Peter Ndumbe (Cameroon) • Marcel Tanner (Switzerland) • Douglas Wassenaar (South Africa) • John Williams (France)
Type of Project:	Support for courses on ethics
Goal:	The aim of TRREE for Africa is to develop a training programme and capacity building resources in research ethics for all those involved in clinical trials in Africa (e.g. researchers, ethics committees, institutions, research participants and regulators).
Objectives:	1. Increase knowledge as well as practical skills of those involved in the management and conduct of ethics evaluation and research partnerships 2. Create a participatory process that will nourish lasting partnerships with and amongst African as well as other low and middle income partners 3. Create a resource that will facilitate the dissemination of knowledge. Overall, this will strengthen the research ethics evaluation capacities in African and other participating countries.
Cofunders:	• Swiss National Science Foundation (Switzerland) • KFPE – Commission for Research Partnership (Switzerland) • Swiss Academy of Science (SCNAT) (Switzerland) • Swiss Academy of Medical Sciences (SAMS) (Switzerland) • Health Law Institute(Switzerland) • Canadian Institute for Health Research (Canada)
Status:	Completed
Results and Outcomes:	1. Infrastructure / Capacity Development – The three African collaborators received a laptop and the necessary office supplies. 2. Training (resources developed (e.g. manuals) and human capacity developed) – The online training programme was developed (www.trree.org), including national modules for: Mali, Cameroon, Tanzania and Switzerland – All collaborators received personal coaching and two completed three month internships. 3. Networking/collaborations developed – AMANET (Tanzania) – MRTC (Mali) – University of Yaoundé (Cameroon) – Institute of Health Law, University of Neuchâtel (Switzerland)

	– SARETI (South Africa) – West African Bioethics (Nigeria)
Publications:	1. Ateudjieu Jérome, Baume Cédric, Joyce Ikingura, Marie Hirtle, Alassane Niaré and Dominique Sprumont, Training Needs Assessment in Research Ethics Evaluation Among Research Ethics Committees Members in Three African Countries: Cameroon, Mali And Tanzania. *Developing World Bioethics*, 2009 on-line, Vol. 10 (2) August 2010, Pages: 88–98 2. Dominique Sprumont, Formation de base en éthique de la recherche: retour aux sources avec le projet TRREE. *Bioethica Forum* (2009) Vol. 2, n° 2, pp. 79-81

1.1.4 Matsiegui-Gabon-Ethics

EDCTP Project Coordinator:	Pierre-Blaise Matsiegui (Ministry of Public Health, Gabon)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Establishment and support of a National Ethics Committee in Gabon
EDCTP Project Code:	CB.2005.41302.012
EDCTP Project Start Date:	30 July 2007
EDCTP Project End Date:	30 January 2010
Collaborators:	• Dominique Collin (Gabon) • Saadou Issifou (Gabon) • Christa Janko (Austria) • Dominique Sprumont (Switzerland)
Type of Project:	National Ethics Committee
Goal:	The main goal of this project is the establishment of a NEC based on the following activities: 1. Establishment of an administrative structure (office and personnel) for the adequate functioning of an NEC 2. Establishment of procedures for the functioning of the NEC and for guidance of the review process.
Objectives:	1. Development and implementation of standard operational procedures for protocol review and follow-up of research 2. activities and internal structure and functioning 3. Proposition of laws and legal regulations and guidelines for the control of biomedical research in Gabon 4. Ensuring sustainability by looking for new financing possibilities 5. Organising workshops on ethical issues in Gabon 6. Awareness campaign on ethical problems through information, education, and communication for researchers, health workers, communities and the whole country 7. Creation of a documentation centre 8. Networking with other ethics committees in Central Africa and in Africa.
Status:	Completed
Results and Outcomes:	1. Infrastructure / Capacity Development – A computer and printer were purchased. 2. Training (resources developed (e.g. manuals) and human capacity developed) – Establishment of a Gabonese NEC – Establishment of an administrative structure – Establishment of procedures, including implementation of SOPs – Training of NEC members - 64 participants received training on ethics – A webpage has been designed: www.cner-gabon.org/cner/ 3. Networking/collaborations developed – Medical Research Unit (MRU), Albert Schweitzer Hospital in Lambarene – Vienna School of Clinical Research – Université desSciences de la Santé (USS) – Ministry of Science and Research and Ministry of Finance (Gabon) – AMANET (African Malaria Network Trust) – WHO

	– Facultes de Droit des Universités Fribourg etde Neuchatel – Institut Pasteur – UNESCO – The Ethics Committee of the University of Tübingen – The Joseph and Rose Kennedy Institute of Ethics, Georgetown University

1.1.5 Tindana-Navrongo-Ethics

EDCTP Project Coordinator:	Paulina Tindana (Ghana Health Service, Ghana)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	A proposal for strengthening the capacity of six Research Ethics Committees in Ghana
EDCTP Project Code:	CB.2005.41302.004
EDCTP Project Start Date:	21 June 2006
EDCTP Project End Date:	14 November 2007
Collaborators:	• Okyere Boateng (Ghana) • Abraham Hodgson (Ghana)
Type of Project:	Institutional Review Board
Goal:	The aim of this project was to strengthen the capacity of administrators and members of the six ethics review committees in Ghana.
Objectives:	This project was an intervention phase of an initial survey of research ethics committees (RECs) in Ghana, which was conducted in 2005. The initial survey identified logistics and training as the major challenges facing ethics review committees in the country. Therefore, this project sought to support all the six ethics committees in Ghana to overcome these challenges through the provision of office equipment, local training in research ethics for REC administrators, specifically on the operations of RECs and a national conference to create awareness on the role of ethics review in health research and to foster a relationship between all the RECs in Ghana.
Status:	Completed
Results and Outcomes:	1. Infrastructure / Capacity Development – Six desktop computers, six printers, six filing cabinets and six UPS (universal power systems) were purchased for each of the six RECs that received support via this project 2. Training (resources developed (e.g. manuals) and human capacity developed) – The administrators of six RECs received training on developing SOPs and protocol submission forms. A three-day national conference on “Ethics in Human Research in Ghana” was held (5-7 February 2007). 3. Networking/collaborations developed – African Malaria Network Trust (AMANET) – Pan African Bioethics Initiative (PABIN)

1.1.6 Bengo-Malawi-Ethics

EDCTP Project Coordinator:	Joseph Mfutso-Bengo (University of Malawi)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Strengthening the National Health Sciences Research Committee (NHSRC) and College of Medicine Ethics Committee (COMREC)
EDCTP Project Code:	CB.2005.41302.011
EDCTP Project Start Date:	20 October 2006
EDCTP Project End Date:	19 October 2007
Collaborators:	• Mike Kachedwa (Malawi) • Willard Kazembe (Malawi) • Lie Reidar (Norway) • Rosemary Musesengwa (Zimbabwe) • Paul Ndebele (Malawi)
Type of Project:	National Ethics Committee/Institutional Review Board
Goal:	The main goal of the project was to strengthen the two ethics committees in Malawi, namely the College of Medicine Ethics Committee (COMREC) and the National Health Sciences Research Committee (NHSRC) so as to enhance their roles in research oversight, ethical review and clinical trial monitoring as well as to ensure their independence, competence and transparency. This programme has contributed directly towards improving the quality of research conducted in Malawi. The programme has ultimately improved the trust of the research community by the general public. The strengthening of national capacity for ethical review ensures that only research that addresses national health priorities is conducted in Malawi, thereby directly supporting the health system by supporting evidence based decision making. The trial monitoring component has resulted in the improvement of clinical data generated from Malawi and has also resulted in further safeguarding the rights and welfare of research participants. Ultimately the programme has improved the relevance of clinical trials to Malawi and its population.
Objectives:	1. To strengthen the capacities of NHSRC and COMREC in ethical review and clinical trials monitoring 2. To adequately equip the ethics committee offices so that they can be able to perform all their tasks without limitations
Status:	Completed
Results and Outcomes:	1. Infrastructure/capacity development – Four laptops and a motor vehicle were purchased for the committee Secretariat offices 2. Training (resources developed (e.g. manuals) and human capacity developed) – A four day workshop was held during which members of the two ethics committees developed standard operating procedures for the two ethics committees. The standard operating procedures covered various issues including ethical review and clinical trials monitoring so as to ensure that the two committees are using internationally acceptable standard operating procedures 3. Networking/collaborations developed – Pan African Bioethics Initiative (PABIN)
Publications:	1. Mfutso-Bengo, J. (2008). Report on the workshop "Enhancing Clinical Trial Oversight in Malawi". *Malawi*

	Medical Journal (MMJ), 20 (2), 63–64. www.mmj.medcol.mw 2. Mfutso-Bengo, J., Masiye, F., & Muula, A. (2008). Ethical challenges in conducting research in humanitarian crisis situations. *Malawi Medical Journal (MMJ),* 20 (2), 46–49. www.mmj.medcol.mw.

1.1.7 Bengo (Ndebele)-Malawi-Ethics

EDCTP Project Coordinator:	Joseph Mfutso-Bengo (University of Malawi)
EDCTP Call Title:	Support for Courses and Seminars on Ethics
EDCTP Project Title:	Building and strengthening national capacities in ethical review and clinical trials monitoring in Malawi
EDCTP Project Code:	CB.2005.41300.007
EDCTP Project Start Date:	20 October 2006
EDCTP Project End Date:	30 April 2010
Collaborators:	• Mike Kachedwa (Malawi) • Willard Kazembe (Malawi) • Lie Reidar (Norway) • Rosemary Musesengwa (Zimbabwe) • Paul Ndebele (Malawi)
Type of Project:	National Ethics Review Committee/Institutional Review Board
Goal:	This project aimed at building and strengthening the capacities of the College of Medicine Research and Ethics Committee (COMREC) and the National Health Sciences Research Committee (NHSRC) in ethical review and clinical trial monitoring. The two bodies are the only ethics committees in Malawi.
Objectives:	The main objective of the project was to build and strengthen the capacities of the College of Medicine Research and Ethics Committee (COMREC) and the National Health Sciences Research Committee (NHSRC) in ethical review and clinical trial monitoring. The programme targeted ethics committee members, clinical trial monitors, researchers and officials from the Ministry of Health and Population, National Commission for Science and Technology (NCST) as well as all constituent colleges of University of Malawi. The main objective was achieved through the following steps: Strengthening national capacity for ethical review in Malawi Intermediate steps: • Training workshops in research ethics, Good Clinical Practice (GCP) and ethical review were conducted in all regions and an annual national conference was held during the project's duration. Introduction and strengthening of clinical trial monitoring in Malawi Intermediate steps: • Two clinical trial monitors were employed for the two committees (one for each) • Training of clinical trial monitors in clinical trial inspection. • GCP and ethics training workshops • Clinical inspectors/monitors training courses were developed and conducted • Development of SOPs for inspection activities of approved studies.
Status:	Completed
Results and Outcomes:	1. Infrastructure/capacity development – An overhead projector as well as consumables and supplies for the COMREC Secretariat were purchased. 2. Training (resources developed (e.g. manuals) and human capacity developed) – Three annual national conferences were held. During the conferences, members of COMREC, NHSRC and PMPB were trained in research ethics, GCP and ethical review. Two regional training workshops for members

	of NHSRC, COMREC and PMPB as well as researchers in research ethics and GCP were conducted. Two clinical trial inspectors were hired in 2008 and have been inspecting studies approved by COMREC and NHSRC. The clinical trial inspectors have acquired the skills and expertise in clinical trial monitoring, audits and inspections as well as GCP and research ethics. In conjunction with Kendle South Africa and the College of Medicine Research Support Centre, training courses for clinical trial inspectors for COMREC, NHSRC and PMPB were conducted in Malawi, Zimbabwe and South Africa. Standard Operating Procedures (SOPs) have been developed for COMREC, NHSRC and PMPB. Material transfer agreement documents were finalised and are in use by COMREC, NHSRC and PMPB. The review process of clinical trials between the two ethics committees (NHSRC and COMREC) and the regulatory authority (PMPB) has been harmonised. Members of Medical Rights Watch received funding and training. 3. Networking/collaborations developed – Pan African Bioethics Initiative (PABIN) – Southern African Research Ethics Training Initiative (SARETI) – Partnership for Enhancing Human Research Protection in Africa (PEHRP AFRICA) – African Malaria Network Trust (AMANET)
Publications:	1. Mfutso-Bengo, J. (2008). Report on the workshop "Enhancing Clinical Trial Oversight in Malawi". Malawi *Medical Journal (MMJ*), 20 (2), 63–64 2. Mfutso-Bengo, J. (2008). Report on the workshop "Enhancing Clinical Trial Oversight in Malawi". Malawi *Medical Journal (MMJ),* 20 (2), 63–64 3. Ndebele, P., Mfutso-Bengo, J., & Mduluza, T. (2008). Compensating clinical trial participants from limited resource settings in internationally sponsored clinical trials: A proposal*. Malawi Medical Journal (MMJ),* 20 (2), 42–45.

1.1.8 Falusi-Ibadan-Ethics

EDCTP Project Coordinator:	Adeyinka Falusi (University of Ibadan, Nigeria)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Strengthening the Capacity of Research Ethics Committees in Africa
EDCTP Project Code:	CB.2005.41302.008
EDCTP Project Start Date:	22 November 2006
EDCTP Project End Date:	21 November 2008
Collaborators:	• Marie-Charlotte Bouësseau (Switzerland) • Prince Eleh (Nigeria) • Paul Ndebele (Malawi) • W. Ogala (Nigeria) • Paulina Tindana (Ghana) • John Williams (France)
Type of Project:	Institutional Review Board
Goal:	The goal of this project was to provide technical, administrative and material support to the three research ethics committees (RECs) for effective and efficient capacity building for research oversight to their institutions and possibly others in their localities.
Objectives:	4. Document the existing infrastructure, manpower capacity and operational details of the selected RECs to appropriately assess their needs 5. Develop an intervention package of a training programme and provision of a seed grant to improve capacity building and infrastructural facilities to the three sites 6. Monitor and evaluate the outcomes of the intervention package 7. Empower the core group trained to become trainers in their localities 8. Stimulate the development of ethics guidelines with the incorporation of African concepts.
Status:	Completed
Results and Outcomes:	1. Infrastructure / Capacity Development – Desktop computer, printer, UPS, power surge arrestor, scanner and photocopier were provided to each of the three RECs 2. Training (resources developed (e.g. manuals) and human capacity developed) – A four-day training workshop was held (13-16 February 2007) on ethics. Participants from each REC included the Chair, secretary and three other members. The host institution's IRB, Oyo State Ministry of Health Ethics Committee and Nigerian Bioethics Initiative (NIBIN) representatives also participated actively with a total of 255 participants at the opening ceremony and 40 participants at the training sessions. RECs developed Operational Guidelines 3. Networking/collaborations developed – World Health Organization (WHO) – World Medical Association (WMA)

1.1.9 Manafa-NIMR-Ethics

EDCTP Project Coordinator:	Ogenna Manafa (Nigerian Institute of Medical Research, Nigeria)
EDCTP Call Title:	Support for Courses and Seminars on Ethics
EDCTP Project Title:	Capacity strengthening of Nigerian researchers and ethics committee members on ethics
EDCTP Project Code:	CB.2005.41300.006
EDCTP Project Start Date:	20 October 2006
EDCTP Project End Date:	19 October 2008
Collaborators:	• Carel Ijsselmuiden (Switzerland) • Juntra Karbwang (Switzerland) • Abolarinwa Timothy Olusola (Nigeria) • Kolawole Solomon Oyedeji (Nigeria) • Douglas Wassenaar (South Africa)
Type of Project:	Institutional Review Board
Goal:	The goal was to establish a Health Research Ethics Training Centre at the Nigerian Institute of Medical Research (NIMR) with the objective of building institutional and individual capacity in ethics by training researchers, investigators and members of the ethics committee in the country and establishing an ethics committee in other major institutes and universities that conduct biomedical research.
Objectives:	1. Organise ethics workshops and seminars for researchers and ethics committee members both at national and institutional level 2. Train five to 10 resource people who will serve as the centre's trainers together with the participants 3. Organise and conduct Standard Operating Procedure (SOP) workshops for research ethics committee members and also assist ethics committees in developing SOPs for the proper conduct of their ethics committee 4. Survey established ethics committees to ensure that they meet adequate standards 5. Provide a platform for collaboration between Nigeria, African and other northern institutes and promote discussion on contemporary issues and dilemmas of health research ethics in the African context.
Status:	Completed
Results and Outcomes:	1. Training (resources developed (e.g. manuals) and human capacity developed) – A five day training workshop on Human Subject Protection (11-13 June 2007) and Standard Operating Procedures (SOPs) (14-16 June 2007) writing for investigators and members of RECs/IRBs took place. These workshops were attended by 45 participants. A second five day workshop (21-25 April 2008) was held for investigators and members of RECs/IRBs in northern Nigeria–34 participants attended. An evaluation of three ethics committees took place. A survey visit to some of the ethics committees trained during the June and April workshops was held between October and November 2008. 2. Networking/collaborations developed – TDR/WHO which houses the Scientific Initiative for Developing Capacity in Ethical Review (SIDCER) – West African Bioethics Initiative – Nigerian Institute of Medical Research (NIMR)

1.1.10 Moodley-ERECCA-Ethics

EDCTP Project Coordinator:	Keymanthri Moodley (University of Stellenbosch, South Africa)
EDCTP Call Title:	Support for Courses and Seminars on Ethics
EDCTP Project Title:	Enhancing Research Ethics Capacity and Compliance in Africa (ERECCA)
EDCTP Project Code:	CB.2005.41300.003
EDCTP Project Start Date:	18 August 2006
EDCTP Project End Date:	30 November 2008
Collaborators:	• Johan Hattingh (South Africa) • Lyn Horn (South Africa) • Landon Myer (South Africa) • Jimmy Volmink (South Africa)
Type of Project:	Support for courses on ethics
Goal:	The ERECCA project focuses on capacity development in two niche areas in the African context – Good Clinical Practice (GCP) and Research Ethics Review. GCP training has become a compulsory requirement for researchers in South Africa and in other parts of Africa. Most researchers have some form of basic GCP training, but have a need to update this training on a regular basis (either annually or every two to three years).
Objectives:	Intermediate objectives: • To extend refresher GCP courses to a wider audience via WEB CT • To develop new capacity for ethics review. Final objectives: • To improve compliance with national and international standards of ethical review • To expedite the ethics review process via improved training • To strengthen expertise in the ethical conduct of clinical trials in South Africa.
Status:	Completed
Results and Outcomes:	1. Infrastructure/capacity development – A computer was purchased. 2. Training (resources developed (e.g. manuals) and human capacity developed) – Online GCP refresher course was developed – all 12 modules have been developed – 94 delegates have completed the ERECCA programme. REC Seminar was presented to 52 delegates. 3. Networking/collaborations developed – University of Ibadan, Nigeria – University of Zambia – Pan African Bioethics Initiative (PABIN) – Medicines Control Council (MCC) – University of Cape Town (UCT)

1.1.11 Kilama-AMANET-1-Ethics

EDCTP Project Coordinator:	Wenceslaus Kilama (African Malaria Network Trust (AMANET), Tanzania)
EDCTP Call Title:	Support for Courses and Seminars on Ethics
EDCTP Project Title:	Creating web-based research training courses in biomedical research ethics for Africans
EDCTP Project Code:	CB.2005.41300.002
EDCTP Project Start Date:	1 June 2006
EDCTP Project End Date:	13 June 2007
Collaborators:	• Chilengi, Roma (Tanzania) • Francis Crawley (Belgium) • Joyce Ikingura (Tanzania) • Juntra Karbwang (Switzerland) • Souleman Mboup (Senegal) • Joseph Mfutso Bengo (Malawi) • Alwyn Mwinga (Zambia) • Paul Ndebele (Malawi) • Edphose Nfuka (Tanzania) • Godfrey Tangwa (Cameroon)
Type of Project:	Support for courses on ethics
Goal:	This project will develop a web-based training course on basic biomedical research ethics whose curriculum will be developed through a tailormade approach for the African situation.
Objectives:	The objective of this project is to provide training in biomedical research ethics in Africa through creation of a web-based system of offering formal training to Africans using validated course materials. To achieve this, a training faculty of known health research experts in Africa and Europe has been constituted. They will be responsible for development of the course curriculum and facilitate during the pilot workshop. A “user-friendly” training programme will be developed by a select faculty of experienced health research trainers and will be refined by a sample of the target trainees at a workshop. The courses will offer lecture type and other resource materials on several modules. A pass will be mandatory to proceed from one module to the next, and one has to complete a minimum set of modules to be successful.
Status:	Completed
Results and Outcomes:	1. Training (resources developed (e.g. manuals) and human capacity developed) – Ten modules were developed. By closing date of the project 629 people were reported to have undergone on-line training. A ‘call for training workshop’ was held and 25 participants were trained.
Publications:	1. Chilengi, R., Nyika, A., Tangwa, G. B., Noor, R. A., Ramadhani, S. W., Bosomprah, S., & Kilama, W. L. (2013). Role of e-learning in teaching health research ethics and Good Clinical Practice in Africa and beyond. Cambridge Quarterly of Healthcare Ethics, 22, 110-119.

1.1.12 Sewankambo-Makerere-Ethics

EDCTP Project Coordinator:	Nelson Sewankambo (Makerere University, Uganda)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Supporting research through enhancement of the IRB processes at Makerere Medical School
EDCTP Project Code:	CB.2005.41302.010
EDCTP Project Start Date:	12 October 2006
EDCTP Project End Date:	11 October 2009
Collaborators:	• Patrick Cras (Belgium) • Elly Katabira (Uganda) • Steven Kiwuwa (Uganda) • Paul Kutyabami l (Uganda)
Type of Project:	Institutional Review Board
Goal:	The goal was to train faculty staff in ethical processes; establish a tracking system for research activities; strengthen the infrastructure of the Institutional Review Board (IRB) secretariat and its staffing; establish a financing mechanism to ensure sustainability of IRB activities; institute support mechanisms for ethics committee member retention; and carry out operational research on IRB and related ethical processes.
Objectives:	1. Establish a tracking system for research activities at the Faculty of Medicine. IRB standard forms continue to be in use. Through the support of a grant from the African Malaria Network Trust (AMANET), the institution obtained and installed heavily subsidised ProIRB software that is now fully operational. In this software, a database containing information of all projects approved at the institution is stored and continuously updated 2. Establish a system of financial sustainability through institution of IRB review charges. Revenue was collected from new applications for ethical approval 3. Improve the human resource capacity of the IRB Secretariat. Part-time data entry staff were hired to assist the IRB office to capture, as much as possible, all the information from the records that existed prior to acquisition of the database software 4. Improve the infrastructure of the IRB secretariat. All the necessary equipment was fully procured and because of this operations have continued to be efficient 5. Compensate IRB members in carrying out IRB activities. Time compensation allowances for committee members have continued to be paid and this has provided motivation and commitment. These funds are drawn from the resources obtained through charging of IRB fees 6. Train a pool of Faculty of Medicine staff in ethical review processes.
Cofunders:	African Malaria Network Trust (AMANET)
Status:	Completed
Results and Outcomes:	1. Infrastructure/capacity development – Part-time data entrants were hired to assist with data capturing. A laptop, LCD projector, office furniture, chairs, cabins and a printer were purchased 2. Training (resources developed (e.g. manuals) and human capacity developed) – The institution obtained and installed heavily subsidised ProIRB software, which is now fully operational. In this

	software, a database containing information of all projects approved at the institution is stored and continuously updated. Forty ethics committee members attended a health research ethics workshop (15-17 June 2009) as well as a National Ethics Committee Conference (15-17 July 2009) hosted by the Uganda National Council for Science and Technology (UNCST) 3. Networking/collaborations developed – University of Antwerp Ethics Committee – Africa Malaria Network Trust (AMANET)

1.1.13 Holm-Cardiff-Ethics

EDCTP Project Coordinator:	Søren Holm (Cardiff University, UK)
EDCTP Call Title:	Support for Courses and Seminars on Ethics
EDCTP Project Title:	Developing a distance learning research ethics course for East Africa
EDCTP Project Code:	CB.2005.41300.005
EDCTP Project Start Date:	30 October 2006
EDCTP Project End Date:	15 October 2008
Collaborators:	• Heta Gylling (Finland) • Azaveli Lwaitama (Tanzania) • Jan Helge Solbakk (Norway)
Type of Project:	Support for courses on ethics
Goal:	The overall aim of the project is to develop, pilot and finalise a distance learning course in biomedical research ethics that will provide participants from Eastern Africa with the necessary knowledge and skills to act responsibly in their roles as principal investigators, members or chairs of research ethics committees and editors of scientific journals.
Objectives:	A modular course will be developed that can be delivered either as a paper-based course with e-mail support or as a fully web-based course using the Blackboard system (Blackboard is the e-learning system used by the University of Dar Es Salaam and by Cardiff University). The development will consist of the following steps: 1. Drafting of a ten module course covering the main research ethics issues relevant in the region 2. Seminar in Tanzania with key stakeholders from the East African region followed by finalisation of draft 3. Pilot of draft course including evaluation and revision. 4. Running of final course including evaluation 5. The final result will be a course that the University of Dar Es Salaam can continue to run after the project has ended. The European partners agree to provide academic input to the updating of the course for three years after the end of the project.
Status:	Completed
Results and Outcomes:	1. Training (resources developed (e.g. manuals) and human capacity developed) – Online training course developed but had poor sustainability. 2. Networking/collaborations developed – University of Dar Es Salaam – University of Helsinki – University of Oslo

1.1.14 Munyati-MRCZb&c-Ethics

EDCTP Project Coordinator:	Shungu Munyati (Medical Research Council (MRC), Zimbabwe)
EDCTP Call Title:	Support for Courses and Seminars on Ethics
EDCTP Project Title:	Building national capacity for research oversight in Zimbabwe
EDCTP Project Code:	CB.2005.41300.001
EDCTP Project Start Date:	11 June 2006
EDCTP Project End Date:	1 March 2010
Collaborators:	• Rutendo Kuwana (Zimbabwe) • Lie Reider (Noway) • Shungu Munyati (Zimbabwe) • Paul Ndebele (Malawi) • Priscilla Nyambayo (Zimbabwe)
Type of Project:	National Ethics Committee, Institutional Review Board
Goal:	The main goal was to strengthen national capacities in health research ethics, ethical review and clinical trial monitoring, so as to create an enabling environment for the ethical conduct of research in Zimbabwe and to ensure that trials meet international ethical and Good Clinical Practice standards.
Objectives:	1. Strengthening national and institutional ethical review processes and ethics review capacity in Zimbabwe 2. Strengthening of clinical trial monitoring in Zimbabwe.
Status:	Completed
Results and Outcomes:	1. Infrastructure/capacity development – Motor vehicle, laptops, colour printer, LCD projector and digital camera were purchased. 2. Training (resources developed (e.g. manuals) and human capacity developed) – Training on ethics (10-12 April 2006; 10 July 2007; 14 November 2008; 7-8 April 2009; 23-24 April 2009; 11-12 June 2009; 16-18 November 2009) and GCP workshops (5-7 December 2006; 25-26 January 2007; 8-9 March 2007; 28-31 March 2007; 12-13 April 2007; 28-29 June 2007) took place. The National Ethics Committee received training on research ethics (16 February 2006). In total, 762 researchers, students, IRB and CAB members were trained. Eight clinical trial inspectors were trained. 3. Networking/collaborations developed – Medicines Control Authority of Zimbabwe (MCAZ) – Biomedical Research and Training Institute (BRTI) – African Malaria Network Trust (AMANET) – World Health Organization (WHO) – College of Medicine, Malawi

1.1.15 Houngnihin-Benin-Ethics

EDCTP Project Coordinator:	Roch A. Houngnihin (Ministere de la Sante Publique, Benin)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Support project for the establishment and strengthening of the Benin National Ethics Committee
EDCTP Project Code:	CB.2007.41302.012
EDCTP Project Start Date:	22 October 2008
EDCTP Project End Date:	21 October 2010
Collaborators:	• Jules Affodji (Benin) • Ferdinand Guedou (Benin) • Dorothée Kinde Gazard (Benin) • Raouf A. Osséni (Benin) • Eric Pliya (Benin)
Type of Project:	National Ethics Committee
Goal:	This project aimed to contribute to reinforce the capacities of the National Ethics Committee (NEC) in Benin.
Objectives:	This project contributed to the setting up and the reinforcement of the capacities of the National Ethics Committee (NEC). For this objective, many workshops and meetings were organised within the technical recipients, actors and members of the NEC to define a conceptual framework for a homogeneous proposal, in the light of international strategic plans, in order to retain the strategic objectives, the fields of services provisions, essential activities, mechanisms of coordination and monitoring and evaluation. The project coordination will profit by assistance from the WHO local office, EDCTP and international consultants. A plan of transfer of competencies was elaborated and carried out.
Cofunders:	Pfizer
Status:	Completed
Results and Outcomes:	1. Infrastructure/capacity development – Equipment and computers for the Secretariat were purchased 2. Training (resources developed (e.g. manuals) and human capacity developed) – The law on the creation of a National Ethics Committee was revised and adopted by the Parliament. All of the members of the National Ethics Committee were trained on ethics in Benin (Cotonou) (10-12 August 2010; 40 participants). Training on research ethics ("Conducting research responsibly") took place in Kenya (Nairobi) (3-5 October 2010; four participants). Forty five researchers were trained on the role of an ethics committee (for its good knowledge and its perception in Benin). Information leaflets were developed and a website: www.ethique-sante.org 3. Networking/collaborations developed – National institutions: National Ethics Committee, Faculty of Health Sciences, WHO (Benin), Regional Institute of Public Health, Clinapharm/PharmaClin Society, Faculty of Law, Faculty of Human Sciences – Steve Biko Centre for Bioethics - University of Witwatersrand (South Africa)

1.1.16 Petros-ETBIN-1-Ethics

EDCTP Project Coordinator:	Beyene Petros (University of Addis Ababa, Ethiopia)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Strengthening the ethics of health research in Ethiopia
EDCTP Project Code:	CB.2007.41302.017
EDCTP Project Start Date:	29 August 2008
EDCTP Project End Date:	30 April 2010
Collaborators:	• Abraham Aseffa (Ethiopia) • Fisseha Hailemeskel (Ethiopia)
Type of Project:	Institutional Review Board
Goal:	Research departments in the five newly established universities did not have the capacity to establish their own institutional review committees. Therefore, assisting these institutions to form their own Institutional Review Boards (IRBs) and strengthening the existing IRBs in the established institutions falls within the remit of the Ethiopian Bioethics Initiative (ETBIN). Mandate is also given to research and higher learning institutions and health bureaus of regional states to provide ethical clearance to projects that do not require national approval (i.e. small grant projects supported by ESTC or local institutes). The aim was to establish and strengthen Health Research Ethics Committees in Ethiopia.
Objectives:	1. Establishing Institutional Review Boards (IRBs) in five newly established universities 2. Strengthening three existing IRBs 3. Popularising health research ethics in the country.
Cofunders:	Armauer Hansen Research Institute (AHRI, Ethiopia)
Status:	Completed
Results and Outcomes:	4. Infrastructure/capacity development – Eleven printers, 12 computers, one photocopier and one scanner were purchased. 5. Training (resources developed (e.g. manuals) and human capacity developed) – A Human Participant Protection, GCP and SOP Bioethics Training Workshop took place (27-31 July 2009; 6-10 February 2010; 41 participants). Training on health research ethics was provided to five new IRB members (27-31 July 2009). A second training session on ethics for IRB members from universities and research institutions that have existing IRBs took place (6-10 February 2010) for 35 participants. A 35-page popularisation manuscript on Human Participant Protection and Good Clinical Practice (GCP) was prepared in Amharic (Ethiopian official language). 6. Networking/collaborations developed – Bioethics Unit, School of Medicine, Addis Ababa University (AAU) – Pan African Bioethics Initiative (PABIN)

1.1.17 Adebamowo-WABT-Ethics

EDCTP Project Coordinator:	Clement Adebamowo (West African Bioethics Training Program, Nigeria)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Strengthening the National Health Research Ethics Committee of Nigeria (NHREC)
EDCTP Project Code:	CB.2007.41302.001
EDCTP Project Start Date:	29 August 2008
EDCTP Project End Date:	28 August 2010
Collaborators:	• Yakubu Aminu (Nigeria) • Yemisi Ajibose (Nigeria)
Type of Project:	National Ethics Commiteee
Goal:	The objective of this work was to provide training for members of theNational Health Research Ethics Committee of Nigeria in order to strengthen the committee in carrying out its mandate as defined by the National Code for Health Research Ethics, Nigeria government laws and regulations.
Objectives:	1. Provide training in health research ethics for those members of the NHREC who have not had specific training in health research ethics 2. Increase the capacity of the NHREC members to review research protocols and contribute to policy formulation in health research ethics for Nigeria.
Cofunders:	West African Bioethics Training Program (Nigeria)
Status:	Completed
Results and Outcomes:	1. Training (resources developed (e.g. manuals) and human capacity developed) – Thirteen participants received training in a course on “Informed Consent and Management of an Ethics Committee” (April 2009). In June 2010, 10 members from the National Health Research Ethics Committee (NHREC) received materials (e.g. books) and training towards a diploma in research ethics at the West African Bioethics Training Programme (WABTP) based at the University of Ibadan. 2. Networking/collaborations developed – Federal Ministry of Health of Nigeria

1.1.18 Wane-Rwanda-Ethics

EDCTP Project Coordinator:	Justin Wane (Rwanda National Ethics Committee, Rwanda)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Strengthening of the Rwanda National Ethics Committee
EDCTP Project Code:	CB.2007.41302.013
EDCTP Project Start Date:	15 September 2008
EDCTP Project End Date:	14 September 2011
Collaborators:	• Dariya Mukamusoni (Rwanda) • Emmanuel Nkeramihigo (Rwanda)
Type of Project:	National Ethics Committee
Goal:	The Rwanda National Ethics Committee (RNEC) was created in 2002 by the Minister of Health. It is currently composed of 10 members: a chairperson, a vice-chair, a secretary, a treasurer and seven other members. It is gender balanced and has laypersons representing the community. The committee meets on a monthly basis and has drafted Standard Operating Procedures (SOPs). An administrator was recruited with the responsibility of running the office on a day-to-day basis. The Ministry of Health allocated an office to the committee and provided basic infrastructure in the form of an old computer and printer as well as desks and shelves. The lack of appropriate infrastructure, expertise and resources are major constraints. The project intended to strengthen the process of review of the ethics of research related to healthcare by improving the infrastructure available to the functioning of the RNEC and improve the committee's expertise by providing continuous training.
Objectives:	The plan is to strengthen the National Ethics Committee by: 1. Training in human subject's protection course 2. Completion of SOPs 3. Training in SOPs 4. Improvement of the infrastructure, internet and telephone connectivity 5. Acquisition of shelves and metal lockable cabinets for archiving documents 6. Providing a stable salary to the administrator 7. Publish guidance documents, such as RNECs SOPs National Guidelines on the Ethics of Health Related Research in Rwanda 8. Setting up a website providing access to guidance documents and important links 9. Meeting to discuss with research community, national workshop to explain procedures, e.g. SOPs, forms 10. Propose National Guidelines for Ethical Review 11. Organise training of local IRBs and teaching of ethics in health training institutions 12. Networking activities with dissemination of information.
Status:	Completed
Results and Outcomes:	1. Infrastructure/capacity development – The following items were purchased: one computer, one printer, one refrigerator, one office utensil cabinet, shelves, one coffee table, five chairs and three lockable cupboards for archiving documents. Infrastructure has been improved, namely internet and telephone connectivity. The office and meeting room were painted. A website was developed

	(www.rnec.moh.gov.rw). The grant provided capacity to cover staff salaries including one for a short-term administrator when the administrator attended training abroad 2. Training (resources developed (e.g. manuals) and human capacity developed) – SOPs for the RNEC were developed. A training course in Human Subjects Protection was conducted (12-14 July 2010) – 21 participants were trained. Local IRBs were trained and local IRBs were established. This grant allowed institutional capacity strengthening for the RNEC where five board members and the administrator attended different training sessions/conference abroad. The project facilitated site visits to monitor implementation of approved protocols 3. Networking/collaborations developed – African Vaccine Regulatory Forum (AVAREF) – Africa Malaria Network Trust (AMANET) – International Partnership for Microbicides (IPM) – International AIDS Vaccine Initiative (IAVI) – Mapping African Research Ethics and Drug Regulatory Capacity (MARC) – Centers for Disease Control (CDC) – Public Responsibilty in Medicine and Research (PRIM&R) – FWA – Western Institution Review Board in Olympia (United States of America)

1.1.19 Changalucha-NIMR-Ethics

EDCTP Project Coordinator:	John M. Changalucha (National Institute for Medical Research (NIMR), Tanzania)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Establishment of Ethics Review Board (ERB) in Mwanza, Tanzania and collaboration between local and national IRBs
EDCTP Project Code:	CB.2007.41302.018
EDCTP Project Start Date:	29 August 2008
EDCTP Project End Date:	28 February 2010
Collaborators:	• Zaba Basia (United Kingdom) • Joyce Ikingura (Tanzania) • Saidi Kapiga (Tanzania)
Type of Project:	Institutional Review Board
Goal:	The establishment of a well-functioning local Institutional Review Board (IRB) with members trained in Tanzania; clear terms of reference; a Secretariat to support its operations; developed SOPs and guidelines on conducting ethical health review; a forum for local IRBs and strengthened collaboration between local IRBs and the National Ethics Committee.
Objectives:	The main objective of this project was to establish a local IRB to serve institutions conducting medical research in the Lake Victoria and Western zones of Tanzania; and to strengthen collaboration between the local IRBs in major Tanzanian health research institutions and the National Ethics Committee. A steering committee was formed to guide the establishment of a local ethics review board (ERB) in Mwanza, Tanzania. Members of the ERB were trained in research ethics.
Status:	Completed
Results and Outcomes:	1. Infrastructure/capacity development – Equipment including two computers, one laser printer, three filing cabinets and one photocopier machine were purchased. 2. Training (resources developed (e.g. manuals) and human capacity developed) – A steering committee was formed to establish the IRB, SOPs were developed and a secretariat was formed. A two day training workshop for 16 participants was conducted in order to orient IRB members on Health Research Ethics (HRE), their duties and responsibilities (5-6 March 2009). The first National Workshop of Health Research Ethics Review Committees and Regulatory Authorities was held in order to share experiences between all active IRBs in Tanzania (21 March 2009; 21 participants). 3. Networking/collaborations developed – Bugando Medical Centre – African Medical and Research Foundation (AMREF) – Sekou Toure Hospital – Tanzania Essential Strategies Against AIDS (TANESA)

1.1.20 Chilengi (Kilama)-AMANET-2-Ethics

EDCTP Project Coordinator:	Roma Chilengi (Wenceslaus Kilama) (African Malaria Network Trust, Tanzania)
EDCTP Call Title:	Support for Courses and Seminars on Ethics
EDCTP Project Title:	Continuation and expansion of the web based learning platform to more courses
EDCTP Project Code:	CB.2007.41300.001
EDCTP Project Start Date:	25 February 2008
EDCTP Project End Date:	24 February 2009
Collaborators:	• Joyce Ikingura (Tanzania) • Joseph Mfutso-Bengo (Malawi) • Paul Ndebele (Malawi) • Edephonse Nfuka (Tanzania) • Godfrey Tangwa (Cameroon) • Paulina Tindana (Ghana) • Aceme Nyika (Tanzania) • Ramadhani Noor Abdalla (Tanzania) • Saad Ramadhani (Tanzania) • William Mwatu (Kenya) • Djouaka Rousseau (Benin)
Type of Project:	Support for courses on ethics
Goal:	This one year project was funded to carry forward work from the previous grant that supported creation of a web based Health Research Ethics (HRE) course at the African Malaria Network Trust (AMANET).
Objectives:	The project supported continuation of the basic HRE course; creation of a French version of the basic HRE course, an Advanced HRE course; and a Good Clinical Practices (GCP) course. The other key expected outcomes of this new effort include the following: 1. Improved delivery of the web based course with new features 2. Increased francophone Africa participation on the basic course 3. Further training for individuals interested in higher understanding of research ethics 4. Using the web learning to deliver GCP training.
Cofunders:	African Malaria Network Trust (AMANET, Tanzania)
Status:	Completed
Results and Outcomes:	1. Training (resources developed (e.g. manuals) and human capacity developed) – A new platform licence was procured. The basic HRE course was successfully translated into French. The web-based GCP course was released. Advanced HRE course was designed.
Publications:	1. Chilengi, R., Nyika, A., Tangwa, G. B., Noor, R. A., Ramadhani, S. W., Bosomprah, S., & Kilama, W. L. (2013). Role of e-learning in teaching health research ethics and Good Clinical Practice in Africa and beyond. *Cambridge Quarterly of Healthcare Ethics*, 22, 110-119.

1.1.21 Massaga-TANHER-Ethics

EDCTP Project Coordinator:	Julius J. Massaga (National Institute for Medical Research (NIMR), Tanzania)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Strengthening ethical standards and practices in the protection of participants in health research in Tanzania
EDCTP Project Code:	CB.2007.41302.005
EDCTP Project Start Date:	16 September 2008
EDCTP Project End Date:	15 March 2010
Collaborators:	• Andrew Kitua (Tanzania) • Mwele Malecela (Tanzania) • Leonard Mboera (Tanzania)
Type of Project:	National Ethics Committee
Goal:	The Tanzania Health Research Forum (TANHER-Forum) was established in 1999 as a body corporate of partner institutions in health research in Tanzania. The project planned to strengthen ethical conduct of health research in Tanzania.
Objectives:	The aim of the project was to strengthen ethical conduct of health research in Tanzania through the following activities: 1. Review the National Guidelines for Health Research in Tanzania developed in 2001 in order to take into account recent developments in health research including molecular biology, genomics and research on emerging diseases and clinical trials 2. Build capacity of the TANHER-Forum for improved efficiency and effectiveness by strengthening the office management through procurement of office furniture and modern office equipment (computer, network printer, photocopy machine, scanner with advanced document feeder), for facilitating storage and retrieval of information 3. Develop national guidelines for insurance and compensation of research participants involved in clinical trials 4. Organise a stakeholders meeting to disseminate the revised guidelines, SOPs and guidelines on insurance and compensation of clinical trials research participants.
Status:	Completed
Results and Outcomes:	1. Infrastructure/capacity development – Office furniture (two tables and two office chairs), cabinets (two units), desktop computers (two units), laptop (one unit), printer (one unit), photocopier (one unit), scanner with advanced document feeder (one unit) and UPS (two units) were purchased. 2. Training (resources developed (e.g. manuals) and human capacity developed) – Stakeholder's workshop (10 September 2008); stakeholder's meeting to discuss insurance of clinical trials participants in Tanzania (08 June 2010; 29 participants); workshop to develop proposal on reduction of maternal and new-born mortality in Tanzania (August 2010); and a symposium on research ethics in clinical studies in sub-Saharan Africa (05-07 April 2011) were held. The National Guidelines on ethics for health research in Tanzania (2nd version, 2009) was revised. Standard Operating Procedures for the National Ethics Review Committee in Tanzania

	(www.nimr.or.tz/ethical_guidelines.html) were developed. Guidelines on Insurance of Clinical Trial Participants were developed.

1.1.22 Onapa-UNCST-Ethics

EDCTP Project Coordinator:	Maxwell Otim Onapa (Uganda National Council for Science and Technology, Uganda)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Strengthening the national scientific and ethical review system and process in Uganda
EDCTP Project Code:	CB.2007.41302.007
EDCTP Project Start Date:	5 September 2008
EDCTP Project End Date:	4 September 2011
Collaborators:	• Julius Ecuru (Uganda) • Leah Nawegulo (Uganda) • Jane Nabuto (Uganda) • Winfred Badanga (Uganda)
Type of Project:	National Ethics Committee
Goal:	The goal of this project is to strengthen the National Scientific and Ethical Review System and process in Uganda through improving the efficiency, effectiveness and coordination of the national system for scientific and ethical review of research protocols.
Objectives:	1. To ensure that a minimum standard is applied for post-approval monitoring of research 2. To develop the accreditation standards for all institutional review/ethics committees (IRCs) based on the existing national and international human subject's protection guidelines 3. To develop standard operating procedures (SOPs) for the National AIDS/HIV Research committee (NARC) in Uganda 4. To establish a network of IRC chairpersons for an improved coordination of the ethical review system in Uganda 5. To organise and launch the First Annual Research Ethics Conference. 6. To improve the infrastructure for the NARC and Health Sciences Committee.
Status:	Completed
Results and Outcomes:	1. Infrastructure/capacity development – The following equipment was purchased: one desktop computer and accessories, two laptops, one LCD projector, one scanner, one printer, one paper shredder, two office tables and two office chairs. 2. Training (resources developed (e.g. manuals) and human capacity developed). Foundational Research Ethics Training course was launched at the first ANREC. Organised and hosted the Annual Research Ethics Conference (ANREC) (15-17 July 2009; 14-16 July 2010 and 13-15 July 2011). SOPs for the National HIV/AIDS Research Committee (NARC), a committee of the Uganda National Council for Science and Technology, were developed and approved. Educational materials in research ethics were developed (training manual). A network of IRC Chairpersons in Uganda was established. 3. Networking/collaborations developed – Uganda Virus Research Institute (UVRI) – Makerere University – Gulu University – Lacor Hospital

	– Mbarara University of Science and Technology – Mbale Regional Hospital – Vector Control Division, Ministry of Health – Mildmay Uganda – The AIDS Support Organization (TASO) – Joint Clinical Research Centre (JCRC) – Mengo Hospital

1.1.23 Mason-BRTI-Ethics

EDCTP Project Coordinator:	Peter Mason (Biomedical Research and Training Institute (BRTI), Zimbabwe)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Establishing an Ethics Research Unit
EDCTP Project Code:	CB.2007.41302.008
EDCTP Project Start Date:	24 July 2008
EDCTP Project End Date:	30 September 2009
Collaborators:	• Jens Mielke (Zimbabwe)
Type of Project:	Institutional Review Board
Goal:	The conduct of ethical review of human subject's research in Zimbabwe is constrained by the limited facilities and human resources available to conduct an efficient review process. Improved training and information dissemination are needed to imrove this situation.
Objectives:	1. Provide administrative support to the BRTI-IRB 2. Provide a forum for discussion on ethical review problems in Zimbabwe 3. Produce a booklet with relevant case studies to use in training IRB and ERC members and researchers in Zimbabwe 4. Improve information dissemination through an online newsletter that discusses ethical issues in research.
Status:	Completed
Results and Outcomes:	1. Infrastructure/capacity development – A fully fledged and standalone unit was established within the BRTI. Wireless connectivity to the internet, computers, printers and office furniture were purchased. 2. Training (resources developed (e.g. manuals) and human capacity developed) – Publication of an ethics handbook and ARENA newsletter. Workshop on 'ethical issues in health research in Africa' (23 March 2009; 43 participants) and an ethics training course (24-27 March 2009; 21 participants) were held.

1.1.24 Khulumani-Botswana-Ethics

EDCTP Project Coordinator:	Pilate Khulumani (Ministry of Health Botswana)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Strengthening of the Botswana IRB, and establishment of Health Institutions and Health Districts Ethics Committees
EDCTP Project Code:	CB.2008.41302.012
EDCTP Project Start Date:	23 February 2010
EDCTP Project End Date:	22 February 2013
Collaborators:	• David Guwatudde (Uganda) • Keymanthri Moodley (South Africa) • Paul Ndebele (United States of America)
Type of Project:	National Ethics Committee, Institutional Review Board
Goal:	The goal of this project is to strengthen the capacity of Botswana's National Research Ethics Committee (BNREC) through training its members in general ethics principles, structure of good clinical practice and new developments in biomedical research associated with ethical review of clinical trials in order to empower members with the knowledge and skills necessary to carry out their mandate. The project is also meant to assist in training BNREC members to audit and monitor clinical trials at all stages and to develop a well documented system. Community Advisory Boards (CABs) will also be set up as part of this project to sensitise communities in Botswana about health research, especially clinical trials conducted in their communities. This project aims to target the multinational organisations that conduct clinical trials in Botswana e.g. The Botswana Harvard Partnership, The Botswana-USA (BOTUSA) collaboration, Baylor Children's Centre of Excellence that deals with antiretroviral treatment in children, The University of Pennsylvania, The University of John Hopkins, The University Research, CIET, University of Botswana and many other research organisations that are based in Botswana. A strong IRB will assist in reducing delays encountered in clearing clinical trial proposals submitted by the above organisations. In addition, strengthening the IRB will build human resource capacity and improve research ethics standards.
Status:	Completed
Objectives:	1. Strengthen the Botswana National Research Ethics Committee (NREC) and establish Institutional Review Boards (IRBs) 2. Sensitise and increase awareness in communities on the values of clinical trials and the ethical conduct of relevant research in their communities as well as the obligation of investigators to protect the rights, safety and welfare of research participants and communities 3. Establish IRBs in all health training institutions and districts in Botswana 4. Train ethics committee members in the ethical and scientific review of research proposals as well as auditing and monitoring of approved studies, especially clinical trials 5. Develop review guidelines, Standard Operational Procedures (SOPs) and Clinical Trial Guidelines 6. Improve office infrastructure through purchasing

	equipment and stationery.
Results and Outcomes:	1. Infrastructure/capacity development - One laptop, one heavy duty photocopier, one camera, one printer, four filing cabinets and one shredder were purchased. 2. Training (resources developed (e.g. manuals) and human capacity developed) - Two seminars on research ethics were held in collaboration with the University of Pennsylvania and University of Botswana (16-17 September 2010; 22 participants) and (8-9 December 2010; 22 participants). Clinical trials training took place (8-9 June 2010; 27 participants). Three Community Advisory Board Workshops took place (23-24 September 2010; 21 participants); (23-24 February 2010; 22 participants) and (28 March 2011; 24 participants). Three workshops for NREC members and one audit training took place (12-13 December 2011; 14 participants). CABs have been established in three districts. A CAB workshop took place (9 November 2011; 18 participants). Five out of seven Institutes of Health Sciences have established their own ethics committee. Review guidelines and SOPs were developed. Members from Serowe Institute of Health Sciences (28-29 November 2011; 30 participants), Sekgoma Memorial Hospital, Kanye Seventh Day Adventist School of Nursing (22-23 November 2011; 29 participants) and Serowe College of Education received training. Application forms, consent forms and a review checklist were developed for students' research. Two IRBs received training: Letsholathebe Memorial Hospital (21-22 February 2012; 17 participants) and Nyangabwe Referral Hospital. Three members from the secretariat and one IRB member visited South Africa on a bench marking exercise (13–17 March 2012). One member of staff from the Health Research and Development Division completed a two week short course on ethics at Stellenbosch University (11-22 February 2013). Training of Deborah Retief Memorial Hospital-School of Nursing IRB on ethics in health research was conducted in Mochudi (25-26 June 2012; 22 participants). Two CABs were established and trained in Kanye (Southern District) (13-14 September 2012; 20 participants) and Serowe (Central District) (18-19 September 2012; 13 participants). Members from the IRB and BNREC (Botswana National Research Ethics Committee) completed the online Collaborative Institutional Training Initiative (CITI) programme. 3. Networking/collaborations developed – University of Pennsylvania – University of Botswana – University of Stellenbosch – Botswana Harvard Partnership – Harvard School of Public Health – Boehringer-Ingelhiem – Makerere University – Baylor College of Medicine – Mapping African Research Ethics and Drug Regulatory Capacity (MARC) – Council for Scientific and Industrial Research (CSIR)

	(South Africa) – University of Limpopo-MEDUNSA Campus (South Africa) – Human Science Research Council (HSRC) (South Africa) – National Health Research Ethics Council (NHREC) (South Africa)
Publications:	1. Barchi, F. H., Kasimatis-Singleton, M., Kasule, M., Khulumani, P., & Merz, J. F. (2013). Building research capacity in Botswana: A randomized trial comparing training methodologies in the Botswana ethics training initiative. *BMC Medical Education*, 13:14. http://www.biomedcentral.com/1472-6920/13/14

1.1.25 Mupenda-CIBAF-Mzadi-Ethics

EDCTP Project Coordinator:	Bavon Mupenda (Centre Interdisciplinaire de Bioéthique pour L'Afrique Francophone (CIBAF), Democratic Republic of Congo)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	The Mzadi project: Strengthening research ethics capacity in the Republic of Congo-Brazzaville and the Democratic Republic of Congo
EDCTP Project Code:	CB.2008.41302.014
EDCTP Project Start Date:	18 December 2009
EDCTP Project End Date:	17 December 2010
Collaborators:	• Stephane Leyens (Belgium) • Jean-Vivien Mombouli (Congo Brazzaville) • Félicien Munday (Democratic Republic of Congo) • Stuart Rennie (United States)
Type of Project:	Institutional Review Board
Goal:	The primary aim of this project was to strengthen the capacity of the ethics committee at Marien Ngouabi University, enabling the latter to conduct high quality ethical review of submitted scientific protocols.
Objectives:	1. Establish sustainable, mutually supportive relationships between the research ethics committees of Marien Ngouabi University (Brazzaville, Republic of Congo) and the Kinshasa School of Public Health (Kinshasa, Democratic Republic of Congo) 2. Increase the capacity of ethics committee members at both institutions to contribute to policy formation regarding research ethics in their respective countries 3. Enhance the culture of research ethics at both institutions through south-to-south educational activities among key stakeholders in the health research enterprise.
Status:	Completed
Results and Outcomes:	1. Infrastructure/capacity development – Desks and tables (four in total), one laptop and one inkjet printer were purchased. 2. Training (resources developed (e.g. manuals) and human capacity developed) – SOPs were finalised, national guidelines were developed and a researcher's brochure were developed. A webpage on the existing website was created to assist researchers with the ethical review process. A two day guideline development workshop was held. Four research ethics seminars and workshops at both Brazzaville and Kinshasa, which targeted different populations, were conducted. Research ethics invited seminars involved a restricted group (15 participants and three technical assistants) of experienced researchers, clinicians, nurses and university administrators involved in biomedical research. 3. Networking/collaborations developed – Marien Ngouabi University – Kinshasa School of Public Health – University of North Carolina–Chapel Hill – University of Namur (Belgium)

1.1.26 Okitolonda-CIBAF-Palabre-Ethics

EDCTP Project Coordinator:	Emile Okitolonda Wemakoy (Centre Interdisciplinaire de Bioéthique pour L'Afrique Francophone (CIBAF), Democratic Republic of Congo)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	The Palabre project: Developing national research ethics guidelines for the Democratic Republic of Congo
EDCTP Project Code:	CB.2008.41302.025
EDCTP Project Start Date:	16 February 2010
EDCTP Project End Date:	15 February 2011
Collaborators:	• Guillaume Louis Kiyombo (Democratic Republic of Congo) • Mampunza Ma Miezi (Democratic Republic of Congo) • Stuart Rennie (United States)
Type of Project:	National Ethics Commitee
Goal:	This project aimed at strengthening the capacity of the National Health Ethics Council (NHEC) and developing national ethics guidelines.
Objectives:	1. Strengthening the capacity of the National Health Ethics Council. Activities in support of this aim included: – Formation of an ethics working group, including the Centre Interdisciplinaire de Bioéthique pour l'Afrique Francophone (CIBAF) members and members of the National Health Ethics Council – Training members from the National Health Ethics Council who have not had formal research ethics education, including extensive review of other national research ethics guidelines – Drafting of Standard Operating Procedures (SOPs) for the Council, and finalising its constitution and mandate. 2. Developing national ethics guidelines for biomedical and public health research. Activities in support of this aim include: – Drafting of national guidelines for medical and public health research in the Democratic Republic of Congo – Holding public panel discussions regarding the national ethics guidelines, and incorporating feedback into the final version – Dissemination of guidelines on the Democratic Republic of Congo – Ministry of Health website and publishing summaries of the guidelines in the national press.
Status:	Completed
Results and Outcomes:	1. Infrastructure/capacity development – Two laptops, four desks/ tables and one printer were purchased. 2. Training (resources developed (e.g. manuals) and human capacity developed) – SOPs were developed. National guidelines for medical and public health research in the Democratic Republic of the Congo were drafted. Members of the National Health Ethics Council received training (11 participants). A National Research Ethics Guidance workshop was organised inviting participants from the following groups and institutions: members of research ethics committees; local stakeholders in the health research enterprise (representatives from the Ministry of Health, members of the National AIDS and TB

	Control Boards, principal investigators of local research projects, hospital and clinic directors, local health-related NGOs, local human rights organisations, pharmaceutical company representatives); interested members from the general public, including participants from the 11 provinces that compose the DRC. 3. Networking/collaborations developed – Human African Trypanosomiasis Platform

1.1.27 Boateng-NMIMR-Ethics

EDCTP Project Coordinator:	Okyere Boateng (University of Ghana)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Establishment of National Research Ethics Committee and strengthening of newly established IRBs and RECs in Ghana
EDCTP Project Code:	CB.2008.41302.016
EDCTP Project Start Date:	18 December 2009
EDCTP Project End Date:	31 March 2011
Collaborators:	• Isaac Adams (Ghana) • John Gyapong (Ghana) • Paulina Tindana (Ghana) • Abraham Hodgson (Ghana)
Type of Project:	National Ethics Committee, Institutional Review Board
Goal:	The project was put forward to address some ethical concerns related to the general research ethics environment in the country. Research proposals intending to use human subjects as participants have to undergo ethical review to address issues concerning the protection and welfare of the research participants. As such it is necessary to ensure that reviewers have the requisite skills and knowledge to help in the review of proposals.
Objectives:	1. Enhance the quality of the scientific and ethical review of proposals/protocols involving human subject/participants by ethical review committees through capacity building 2. Develop National Ethical Guidelines in the conduct of research involving human subjects 3. Establish a database for Institutional Review Boards (IRB)/Research Ethics Committees (RECs) in the country 4. Promote networking and sharing of ideas among IRB/REC and researchers 5. Resource IRBs/RECs that were not covered by the earlier grant from EDCTP by providing them with office equipment.
Status:	Completed
Results and Outcomes:	1. Infrastructure/capacity development – Four computers, four printers, four cabinets and five shredders were purchased. The target institutions for the supply of equipment were: – The University of Ghana Medical School (UGMS) Ethics and Protocol Review Committee – The Centre for Scientific Research into Plant Medicine (CSRPM) Institutional Review Board – The University of Development Studies (UDS) Institutional Review Board – The Secretariat, National Health Research Ethics Board – Noguchi Memorial Institute for Medical Research 2. Training (resources developed (e.g. manuals) and human capacity developed) – A two day Health Research Ethics seminar was held (17-18 November 2010; 36 participants) for researchers, IRB members and lecturers. The training and mentoring of IRB administrators from the eight IRBs took place throughout the programme/period. A two day National Research Ethics Review Conference for Stakeholders was held on 08 and 09 March 2011. National Research Ethics Guidelines drafted. New IRBs

	have received training and guidelines in developing their SOPs. In the process, already established IRBs reviewed their SOPs. Establishment of a Secretariat to work towards establishment of the National Health Research Ethics Board. Improved databases for the IRBs 3. Networking/collaborations developed – African Malaria Network Trust (AMANET) – Kenya Medical Research Institute (KEMRI) – Networking among the local IRBs

1.1.28 Wasunna-KEMRI-Ethics

EDCTP Project Coordinator:	Christine Wasunna (Kenya Medical Research Institute (KEMRI), Kenya)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Strengthening capacity for ethics review and monitoring of approved projects at the Kenya Medical Research Institute
EDCTP Project Code:	CB.2008.41302.024
EDCTP Project Start Date:	18 December 2009
EDCTP Project End Date:	31 May 2012
Collaborators:	• Juma Rashid (Kenya) • Jayesh Pandit (Kenya)
Type of Project:	Institutional Review Board
Goal:	The project aims to build capacity for ethics review and monitoring of Kenya Medical Research Institute's (KEMRI)-approved studies and strengthen research oversight through partnership with the Pharmacy and Poisons Boards' Expert Committee on Clinical Trials (PPB ECCT). The proposed activities are considered critical in enhancing adoption of internationally accepted ethics review standards at KEMRI and to heighten monitoring of new and existing drugs for spontaneous adverse drug reaction. The goal of the project is to strengthen research ethics capacity and provide a framework auditing research approved by the KEMRI ERC and PPB ECCT. The KEMRI ERC currently serves as the national ethics review board. They propose, within one year, to train members at KEMRI/National Ethics Review Committee (KEMRI NERC) and PPB ECCT, in Good Clinical Practices (GCP) and research monitoring through KEMRI's Centre for Clinical Research (CCR). The core activities in year two include establishing a research audit package and initiating a joint electronic clinical trials database between the two institutions.
Objectives:	1. Improve the ethical review process at KEMRI through: – Training KEMRI ERC members in international health research ethics – Facilitating health research ethics workshops for researchers at KEMRI and PPB twice a year. 2. Develop a system for auditing research approved for implementation by the KEMRI ERC in order to provide important research safeguards by: – Facilitating three clinical research monitoring and GCP workshops (three workshops) for site auditors (senior research officers selected from three KEMRI Research Centres in Nairobi, Kisumu and Kilifi); KEMRI ERC and PPB ECCT members – Developing an auditing checklist for project initiation, interim project evaluation and project completion. 3. Promote high standards of clinical research oversight through partnership with the Pharmacy and Poisons Board of Kenya by: – Launching a database on all clinical trials in Kenya – Promoting pharmacovigilance through adverse drug reaction reporting within the study sites.
Status:	Completed
Results and Outcomes:	1. Infrastructure/capacity development - KEMRI ethics review committee received one laptop, one projector and one desktop computer. Pharmacy and

	Poison's Board received: one multipurpose unit comprising a printer, photocopier and scanner; and one desktop computer. 2. Training (resources developed (e.g. manuals) and human capacity developed) - One KEMRI staff member completed a BSc degree in Computer Information Systems at Kenya Methodist University. An electronic submission and review system for clinical trials applications has been developed and implemented at the Pharmacy and Poisons Board (PPB) (www.ctr.pharmacyboardkenya.org). The adverse drug reporting (ADR) system has been reinforced and two tools (Suspected Adverse Drug Reaction Reporting Form and Form for Reporting Poor Quality Medicinal Products) have been developed and promulgated nationally. A Standard Operating Procedure for Routine Monitoring Visits was developed. The following training took place: • Refresher Good Clinical Practice (GCP) and Good Clinical Laboratory Practice (GCLP) (59 participants; 5 July 2010) • Clinical research monitoring (module one) (21 participants; 12-16 July 2010) • Clinical research monitoring (module one: back to basics) (14 participants; 22-26 November 2010) • Clinical research monitoring (module two) (12 participants; 21-25 February 2011) • Clinical research monitoring (modules three and four) (20 participants; 14-17 February 2012 and 20-23 February 2012) • Good Clinical Practice (GCP) and Good Clinical Laboratory Practice (GCLP) (32 participants; 16-18 November 2010) • GCP and essentials of informed consent (18 participants; 28-30 November 2011) • Ethical issues in social science and behavioural studies (17 participants; 30 August 2010) • Genetic and genomic research and data sharing (8 participants; 18 February 2011). 3. Networking/collaborations developed - Pharmacy and Poison's Board (PPB) - Aga Khan University Teaching Hospital - University of Nairobi - Kenyatta National Hospital - Centres for International Programs-Kenya (ICAP-Kenya) - Centre for Research in Therapeutic Sciences (CREATES), Strathmore University, Kenya - National Council for Science and Technology (Kenya) - Consortium for National Health Research (CNHR)

1.1.29 Fumane-Mozambique-Ethics

EDCTP Project Coordinator:	João Manuel de Carvalho Fumane (Ministry of Health/National Institute of Health, Mozambique)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Consolidation of a National Ethic Committees Network in Mozambique by promoting training collaboration with African and European networks
EDCTP Project Code:	CB.2008.41302.019
EDCTP Project Start Date:	16 February 2010
EDCTP Project End Date:	15 February 2012
Collaborators:	• Xavier Carne (Spain) • Raquel Hernandez (Spain) • Nuria Sanz (Spain)
Type of Project:	National Ethics Committee, Institutional Review Board
Goal:	The Mozambican National Ethic Committee, called CNBS (Comité Nacional de Bioéticapara Saúde), was created in 2002. The CNBS coordinated the proposed activities, which consisted of the establishment of a national networking of ethic committees in Mozambique and on strengthening the collaboration with a similar institution in Europe.
Objectives:	To accomplish the goal of the project, training was addressed to members of the existing ethic committees in Mozambique (CNBS and Institutional) and to researchers, other health professionals, health authorities and students from the medical school. The expected outcome of the project was to increase the ethical judgment of ethic committees' members in the view that the Mozambican population should benefit from the relevant research that takes place in their country. On a first step of the training process, the CNBS and IEC members received African Malaria Network Trust (AMANET) and European Clinical Research Infrastructures Network (ECRIN)/Vienna School of Clinical Research (VSCR) training and exchanged capacity building expertise with ECRIN. And on a second step, already trained CNBS and IEC members trained researchers, health professionals, health authorities and medical school students. The second objective was to create a network of Mozambican Institutional Ethics Committees (IECs).
Status:	Completed
Results and Outcomes:	1. Infrastructure/capacity development – One computer, one photocopy machine and two cupboards were purchased. A CNBS protocol database was developed and all protocols were uploaded. 2. Training (resources developed (e.g. manuals) and human capacity developed) – Training on "Ethics committees and clinical trials performed in developing countries" took place in Maputo (29-31 March 2010; 30 participants) – Training on "Regulation for the Institutional Ethics Committees (IEC)" was conducted (24-26 August 2010; 25 participants) – Site visit to ECRIN (European Clinical Research Infrastructures Network: www.ecrin.org), Barcelona, took place (20-24 September 2010) by three members of the CNBS – Training was carried out by the Vienna School for Clinical Research (VSCR) on 22-24 November 2010 in

	Vienna. The topic of the course was “Ethical aspects of clinical research". One member of the CNBS attended the training – Training on “Institutional Review Boards” was conducted in Maputo (25-27 July 2011; 19 participants) – Training on “The use of biological samples” took place in Maputo (19 December 2011; 20 participants) – Training on “The Institutional Review Board in University of Lurio” took place (22-23 April 2012; 17 participants) – In order to standardise procedures for accrediting local institutional ethics committees (IEC), the CNBS has developed rules for IECs. 3. Networking/collaborations developed – Hospital Clinic de Barcelona (Spain) – European Clinical Research Infrastructures Network (ECRIN) – Vienna School for Clinical Research (VSCR) – African Malaria Network Trust (AMANET) – IRB of Catholic University – IRB of National Institute of Health – IRB of Manhiça Health Research Centre – IRB of University of Lurio – IRB of Institute for Health Science

1.1.30 Ukpong-NHVMS-Ethics

EDCTP Project Coordinator:	Morenike Oluwatoyin Folayan Ukpong (New HIV Vaccine and Microbicide Advocacy Society (NHVMAS), Nigeria)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Building capacity of laypersons on IRBs to review research protocols and provide constructive feedback
EDCTP Project Code:	CB.2008.41302.013
EDCTP Project Start Date:	18 January 2010
EDCTP Project End Date:	17 January 2011
Collaborators:	• Bayo Adejumo (Nigeria) • Olayide Akanni (Nigeria) • O Dada (Nigeria) • Bode-Law Faleyimu (Nigeria)
Type of Project:	Support for courses on ethics
Goal:	This project was a proposed follow up to an earlier pilot project with grant support from SIDACTION, France. This project was part of a well thought out systematic capacity building effort for members of IRB institutions in Nigeria. NHVMAS piloted a novel programme to build the capacity of laypersons on IRBs in Nigeria. This was the first ever effort in the country. The initiative was applauded by the National Ethics Board and the Institutional Review Boards from where the trainees came. Laypersons are a subset of community persons who are research gatekeepers for the community. In Nigeria all ethics committees are expected to have at least one layperson on the committee. They are expected not only to address the rights of research participants, but also to address the peculiar needs of their communities. While the role of community oversight is specific to the layperson, for many the capacity to play this role is defective as many are not trained to engage with the research process. This project was specifically designed to address this gap.
Objectives:	1. Provide 20 lay members of the Health Research Ethics Committees in Nigeria with state of the art training on ethical considerations in HIV/AIDS related research over eight months 2. Familiarise 20 lay members of Ethics Committees in Nigeria with the operational guidelines for conducting ethical research in Nigeria over a period of eight months 3. Familiarise 20 lay members of Ethics Committees in Nigeria with the specific issues and principles of design and implementation of HIV prevention and treatment research 4. Enhance the skills of 20 lay Ethics Committee members on reviewing research protocols and providing constructive feedback to those applying for ethical clearance over a period of eight months.
Status:	Completed
Results and Outcomes:	1. Training (resources developed (e.g. manuals) and human capacity developed) – Training manual was developed, printed and distributed. Workshop on how to review a research protocol and provide constructive feedback was conducted – 33 participants were trained. 2. Networking/collaborations developed – National Health Research Ethics Committee – National Bioethics Society of Nigeria

Publications:	1. Folayan, M. O., Adaranijo, A., Durueke, F., Ajuwon, A., Adejumo, A., Ezechi, O., Oyedeji, K., & Akanni, O. Impact of three years training on operations capacities of research ethics committees in Nigeria. *Developing World Bioethics*. 2012 Sep 24. doi: 10.1111/j.1471-8847.2012.00340.x

1.1.31 Sarr-CNRS-Ethics

EDCTP Project Coordinator:	Samba Cor Sarr (Conseil National pour la Recherche en Sante-(CNRS), Senegal)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Programme for strengthening National Research Ethic Committee of Senegal (CNRS) and promoting ethics awareness in Senegal and in West Africa
EDCTP Project Code:	CB.2008.41302.026
EDCTP Project Start Date:	2 December 2009
EDCTP Project End Date:	1 December 2011
Collaborators:	• Charles Becker (Senegal) • Aïssatou Toure (Senegal)
Type of Project:	National Ethics Committee
Goal:	The expected outcomes of this project were the optimisation of the functioning and progressive strengthening of human resources for all the processes of ethic review and follow up of research protocols.
Objectives:	1. The broad objective of the project was to develop the capacity of members of the CNRS for providing competent review of research projects, monitoring the implementation of the projects, and serve as trained trainers. Specific objectives: 2. Improve the human resources of the CNRS Secretariat 3. Improve the infrastructure of the CNRS Secretariat 4. Train the different stakeholders in research ethics: ethic committee 5. members and researchers 6. Improve the review process of health research proposals 7. Establish a tracking system for research proposals 8. Create a website for adequate information for all the stakeholders, awareness and discussion on ethics issues.
Cofunders:	• United Nations Children's Fund (UNICEF) • Council on Health Research for Development (COHRED)
Status:	Completed
Results and Outcomes:	1. Infrastructure/capacity development – Two computers, one laptop, two printers and one video projector were purchased. Literature on ethics and law was purchased for the library. A website was created: http://www.der.sn/ A database was created in order to facilitate the access to information about the protocols examined by the CNERS. 2. Training (resources developed (e.g. manuals) and human capacity developed) – Seventeen participants attended the training and discussion on the SOPs; 21 participants attended the workshop on health research management; and 40 participants attended the workshop on the sharing of health research results. Workshops for conception and validation of working documents as well as writing draft of legal texts on ethics of health research were held. Meetings to review protocols and support experts were held. Five visits to oversee on-going projects in the field were done. The working group produced and harmonised the SOPs. 3. Networking/collaborations developed – Training and Resources in Research Ethics Evaluation

	for Africa (TRREE) – Council on Health Research for Development (COHRED) – The New Partnership for Africa's Development (NEPAD) – West African Health Organisation (WAHO)

1.1.32 Wassenaar-SARECCER-Ethics

EDCTP Project Coordinator:	Douglas Wassenaar (University of KwaZulu-Natal, South Africa)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Strengthening African Research Ethics Committees' capacity for ethical review of HIV prevention research
EDCTP Project Code:	CB.2008.41302.002
EDCTP Project Start Date:	16 November 2009
EDCTP Project End Date:	15 November 2012
Collaborators:	• Mariana Kruger (South Africa) • Catherine Slack (South Africa)
Type of Project:	Support for courses on ethics
Goal:	The Ethics, Law and Human Rights Centre of the WHO/UNAIDS African AIDS Vaccine Programme sponsored by EDCTP funded five African REC members per year to attend two existing and well established SARETI intensive training modules developed and hosted by the South African Research Ethics Training Initiative (SARETI) at the University of KwaZulu-Natal, South Africa. The module content includes institutionalising ethical review of health research and ethical issues in HIV preventative research. The SARETI modules have been taught since 2002 and are run by experts in the topic areas. Each module is formally examined by way of written assignment and formally evaluated by attendees.
Objectives:	The overall objective of the training programme is to strengthen African RECs functioning and capacity to review HIV prevention research. The training programme aims to provide African REC members with advanced theoretical and practical knowledge in the ethical review of complex protocols like HIV prevention trials, and to help institutionalise research ethics review in their home institution.
Status:	Completed
Results and Outcomes:	1. Training (resources developed (e.g. manuals) and human capacity developed) - In 2010, five participants (from Tanzania, Botswana, Liberia, Egypt and Nigeria) completed Module one ('institutionalising ethical review of health research': 6–10 September 2010) and Module two ('ethical issues in HIV preventative research': 13–17 September 2010). In 2011, five African REC members (from Ethiopia, Ghana, Kenya, Nigeria and Zimbabwe) were selected to attend two SARETI modules on 'institutionalising ethical review of health research' (12–16 September 2011) and 'ethical issues in HIV preventative research' (5–9 September 2011). In 2012, five African REC members (from Kenya, Mauritius, Senegal and Tanzania) were selected to attend two SARETI modules on 'institutionalising ethical review of health research' (10-14 September 2012) and 'ethical issues in HIV preventative research' (17-21 September 2012). 2. Networking/collaborations developed – South African National Health Research Ethics Council – Human Sciences Research Council Research Ethics Committee – University of Stellenbosch – Training and Resources in Research Ethics Evaluation for Africa (TRREE)

	– Mapping African Research Ethics and Drug Regulatory Capacity (MARC) – NIH/Fogarty's Medical Education Partnership Initiative (MEPI)
Publications:	1. Kombe, F., Anunobi, E. N., Tshifugula, N. P., Wassenaar, D., Njadingwe, D., Mwalukore, S., Chinyama, J., Randrianasolo, B., Akindeh, P., Dlamini, P. S., Ramiandrisoa, F. N., & Ranaivo, N. (2013). Promoting research integrity in Africa: An African voice of concern on research misconduct and the way forward. *Developing World Bioethics*, 1471-8731.

1.1.33 IJsselmuiden-MARC-Ethics

EDCTP Project Coordinator:	Carel IJsselmuiden (Council on Health Research for Development (COHRED), Switzerland)
EDCTP Call Title:	Support for Courses and Seminars on Ethics
EDCTP Project Title:	Mapping of ethics review and trial regulatory capacity in sub-Sahara Africa
EDCTP Project Code:	CB.2008.41303.001
EDCTP Project Start Date:	19 December 2008
EDCTP Project End Date:	30 June 2012
Collaborators:	Douglas Wassenaar (South Africa)
Type of Project:	Coordination function
Goal:	The MARC (Mapping African Research Ethics and Drug Regulatory Capacity) project aims to develop a map of the capacity to ethically review health research in all African countries where EDTCP operates.
Objectives:	The core deliverables of this project are: 1. A continuously updated ('self-updating'), systematic map of African health research ethics review committees (HRECs) and clinical trial related regulatory activities that are linked to general health research system information of the countries where the ethics committees are located, and is integrated into a global map of health research systems and, where possible, linked with other web-based resources in health research ethics 2. Comprehensive regular reporting on health research ethics activities (capacity programmes and regulatory situation) in sub-Saharan Africa 3. Networking of African regional ethics training initiatives and active HRECs through Health Research Web (HRWeb) and developing the content and display of HREC information in ways that suit the key audiences best 4. Developing sustainability and capacity, in specific: 5. Agreement on criteria for research ethics committee registration on HRWeb 6. Support from donors and research sponsors to demand review by registered research ethics committees 7. Mechanisms for 'self-funding', additional donors in place 8. Beginnings of a pan African accreditation mechanism
Cofunders:	• NIH/Fogarty International Center (United States) • Pfizer (United States)
Status:	Completed
Results and Outcomes:	**Mapping** • One hundred and sixty-six (166) HRECs were identified to be operating across Africa – with great variability in skills, membership and efficiency. The mapped information consists of (1) basic contact information; (2) capacity information which provides detailed quantitative insight into the functions, capacity, resources and needs of the respective HRECs; and (3) HREC support documents • The ethics pages of HRWeb are developed with various analysable functionalities • MARC has an independent website: www.researchethicsweb.org • MARC's platform has found rapid uptake in Latin America and the Caribbean though a collaboration with the Pan American Health Organisation (PAHO). 1008 RECs have been mapped from Latin America (data also available

at: www.researchethicsweb.org). The latter has extensively increased the MARC web strategic users, with an average of 1716 visits recorded in the past three months.

Networking

MARC has launched a research ethics social network platform accessible at www.researchethicsweb.org. The platform is intended to:

- Promote connection and interaction between trainees and staff from HRECs/IRBs in their home countries, also to encourage formation of local activity groups to find solutions to difficult and diverse research ethics questions through blogs, question/answer lists and online discussion forums
- Provide 'closed/private' forums, which enable HRECs to undertake joint review of multi-centre trials. This special feature contributes to the empowerment of less capacitated HRECs. It provides accelerated access to HREC members, ethics trainees and other resource persons active in research ethics and drug regulation
- The success of this initiative will add a new dimension to African research ethics training and capacity building initiatives. It may expand to create a virtual network of trained individuals – a pan African research ethics discussion platform.

Mapping of Medicines Regulatory Authorities (MRAs) commenced in June 2011. To date HRWeb has been adapted to include MRAs information, 16 countries (MRAs) have been mapped, and 54 African countries have been verified as having MRAs.

Meetings

- In September 2011 (26-28), MARC hosted a very successful first ever African Conference for Administrators of Research Ethics Committees (AAREC) in Botswana
- AAREC sought to facilitate a comprehensive understanding of the essential roles, establish a collaborative approach to strengthen and improve the capacity and competence of African research ethics committee administrators, hence, the theme 'striving for quality and efficiency of ethical review of health research in Africa'. A publication based on the proceedings of the AAREC meeting is in the advanced stage of preparation.

Information Management System

- MARC's and COHRED's support to research ethics review capacity in Africa includes the adaptation of the web-based platform that is global to a cloud-based software package for project management for research ethics committees. The package was launched during Forum 2012 in Cape Town under the title of 'RHInnO Ethics' (www.rhinno.net). It is expected that this will revolutionise the efficiency and impact of research ethics review in Africa and beyond
- The overall objective of the RHinnO platform is to provide governments, ethics committees, medicines regulatory authorities, research institutions and networks with a low cost, secure, fully web-based solution for managing and tracking research applications throughout the entire life-

	cycle of the research project • RHinnO will provide quick, reliable and 'real-time' data, tables and graphs that can be used to monitor, evaluate and communicate. The MARC/HRWeb Initiative was positively noted and acknowledged in the landmark December 2011 report of the US Presidential Commission for the Study of Bioethics Issues, titled "Moral science - Protecting participants in Human Subjects Research". The report was commissioned by President Obama at the end of 2010 and was released in December 2011. (see: http://bioethics.gov/cms/sites/default/files/Moral%20Science%20-%20Final.pdf).
Publications:	1. IJsselmuiden, C., Marais, D., Wassenaar, D., & Mokgatla-Moipolai, B. (2012). Mapping African ethical review committee activity onto capacity needs: The MARC initiative and HRWeb's interactive database of RECs in Africa. *Developing World Bioethics*, 12 (2) 74-86.

1.1.34 Mbidde-UVRI-Ethics

EDCTP Project Coordinator:	Edward Katongole Mbidde (Medical Research Council Programme on AIDS - Uganda Virus Research Institute (MRC/UVRI), Uganda)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Strengthening the capacity of the Uganda Virus Research Institute Science and Ethics Committee (SEC) and preparing it for WHO recognition
EDCTP Project Code:	CB.2008.41302.018
EDCTP Project Start Date:	7 February 2010
EDCTP Project End Date:	6 February 2012
Collaborators:	• Tom Lutalo (Uganda) • Robert Ssekubugu (Uganda)
Type of Project:	Imstitutional Review Board
Goal:	There was an urgent need to strengthen the current UVRI (Uganda Virus Research Institute) secretariat by designing and operationalising guidelines and Standard Operating Procedures specific to the type of research work from the partners and core departments. There was also an urgent need to put together guidelines for running the secretariat.
Objectives:	The main objective of the project was to strengthen the review capacity and process of the UVRI Science and Ethics Committee. This required continuing training of the current and potential future members, the scientific staff from the collaborating programs and core UVRI departments. The funds were used to train trainers who would continue with the training process. The funds were also used to strengthen the UVRI Secretariat so that it guides the scientific staff at the Institute on how to write and submit proposals. The process of preparing for the WHO recognition survey was also shared with the other IRBs in the country so that the review process in the country is strengthened. The following is a break-down of the process: • Equipped the science and ethics office with necessary office tools • Prepared the Standard Operating Procedures (SOPs) and regulations for the Science and Ethics Committee • Disseminated SOPs and regulations to the partner programmes • Conducted research site visits to ensure compliance, offered support supervision and continuous training • Facilitated science and ethics review meetings. • Established an IRB forum in the country and liaised with PABIN to strengthen the review process.
Cofunders:	Uganda Virus Research Institute (UVRI)
Status:	Completed
Results and Outcomes:	1. Infrastructure/capacity Development – One desktop computer, one printer, one office table, one UPS, two chairs, one scanner and five constructed filing cabinets were purchased. 2. Training (resources developed (e.g. manuals) and human capacity developed) – SOPs were developed. A team of seven surveyors were trained. With support from this grant, the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) recognition core team trained the local surveyors on recognition/accreditation survey

	techniques. Monitoring visits by SEC members were conducted at six study sites and eight sites were visited for protocol monitoring. A workshop was held on research ethics (2-3 December 2010; 11 participants). 3. Networking/collaborations developed – Medical Research Council-Uganda (MRC) – Rakai Health Sciences Program (RHSP) – Centre for Disease Control-Uganda (CDC) – International AIDS Vaccine Initiative (IAVI) – Uganda National Council for Science and Technology (UNCST) – Joint Clinical Research Centre IRB – Mbarara University IRB – Makerere School of Public Health IRB – Mildmay Uganda

1.1.35 SPRUMONT-TRREE-2-Ethics

EDCTP Project Coordinator:	Dominique Sprumont (Health Law Institute, Switzerland)
EDCTP Call Title:	Support for Courses and Seminars on Ethics
EDCTP Project Title:	Training and Resources in Research Ethics Evaluation for Africa (TRREE for Africa): Extending to Senegal, Nigeria and Mozambique and strengthening the existing Network
EDCTP Project Code:	CB.2009.41302.005
EDCTP Project Start Date:	29 March 2010
EDCTP Project End Date:	28 March 2011
Collaborators:	• Clement Adebamowo (Nigeria) • Samba Cor Sarr (Senegal) • Aïssatou Toure (Senegal) • Eusebio Macete (Mozambique) • Peter M. Ndumbe (Cameroon) • Ogobara Doumbo (Mali) • Wenceslaus Kilama (Tanzania) • Marie Hirtle (Canada) • John R. Williams (Canada) • Marcel Tanner (Switzerland) • Dirk Lanzerath (Germany) • Marie Charlotte Bouësseau (Switzerland) • Douglas Wassenaar (South Africa) • Charles Becker (Senegal) • Dirce Guilhem (Brazil)
Type of Project:	Support for courses on ethics
Goal:	To grow after the initial phase, both in terms of content and countries involved with the programme.
Objectives:	The supported activities have firstly enabled the expansion of TRREE to new countries, namely Senegal, Nigeria and Mozambique, who will benefit from its online training programme and e-resources. Secondly, the online training programme has been made available in Portuguese in addition to the French, English and German versions that have already been developed. This will significantly increase the number of persons who will have direct access to the programme and facilitate further extension and networking in Africa. Thirdly, this new development provides the present TRREE partners with resources to update and upgrade their programmes, thereby offering sustained support to their national and local Research Ethics Committees and strengthening much needed collaboration on research ethics at national and local levels.
Cofunders:	• Swiss National Science Foundation • Institute of Health Law, University of Neuchâtel
Results and Outcomes:	1. Training (resources developed (e.g. manuals) and human capacity developed) – The online training programme (www.trree.org) was extended with four new national modules: – Senegal – Nigeria – Mozambique – Germany – There is also an additional module on informed consent. The programme has been translated into Portuguese. 2. Networking/collaborations developed – African Malaria Network Trust (AMANET) – Comité d'Ethique National de la Recherche en santé

	(CNRS) (Senegal) – European Network of Research Ethics Committees (EURECNET) – Institute of Health Law, University of Neuchâtel (Switzerland) – Manhiça Health Research Center (Mozambique) – Malaria Research & Training Center (MRTC) (Mali) – South African Research Ethics Training Initiative (SARETI) – University of Yaoundé (Cameroon) – West African Bioethics (Nigeria)
Publications:	1. Ateudjieu J., Williams, J., Hirtle, M., Baume, C., Ikingura, J., Niaré, A., & Sprumont, D. (2009). Training needs assessment in research ethics evaluation among research ethics committee members in three African countries: Cameroon, Mali And Tanzania. *Developing World Bioethics*, 10 (2), 88–98. 2. Sprumont, D. (2009). Formation de base en éthique de la recherche: Retour aux sources avec le projet TRREE. *Bioethica Forum*, 2 (2), 79-81.

1.1.36 Matsiegui-CAEN-Ethics

EDCTP Project Coordinator:	Pierre-Blaise Matsiegui (Comité National d'Éthique pour la Recherche du Gabon, Gabon)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Strengthening of the National Ethics Committee in Gabon and creation of a Central African Ethics Committee Network (CAEN)
EDCTP Project Code:	CB.2009.41302.001
EDCTP Project Start Date:	17 May 2010
EDCTP Project End Date:	16 August 2013
Collaborators:	• Sophie Bipolo (Gabon) • Adèle Sambo (Gabon) • Jean Baptiste Moussavou Kombila (Gabon) • Jaqueline Obone Mba (Gabon) • Saadou Issifou (Gabon) • Jean Paul Akue (Gabon) • Christiane Mbili (Gabon) • Véronique Niangui (Gabon) • Dafna Feinholz (France)
Type of Project:	National Ethics Committee
Goal:	A Gabonese National Ethics Committee (NEC) was established with a previous EDCTP grant. Today, the NEC is fully in charge of ethical issues related to research in Gabon (including review of study protocols) and is legally accepted by the Gabonese government. Nevertheless, further selective investment is needed to ensure the sustainability of the Gabonese NEC.
Objectives:	This project is meant to strengthen the Gabonese NEC in a sustainable way by: 1. Investing in infrastructure 2. Providing taylor-made training 3. Raising public awareness in Gabon on ethical issues in (clinical) research as well as the role and responsibilities of the NEC 4. Networking with other African NECs, especially in Central Africa for Creating a Central African Ethics Committee Network (CAEN). The overall expected outcome is a well-established Gabonese NEC working according to international standards and being accepted by and embedded in Gabonese society.
Cofunders:	• Ministry of Public Health (Gabon) • Ministry of Research and Science (Gabon) • Vienna School of Clinical Research (VSCR) (Austria)
Status:	Ongoing
Results and Outcomes:	1. Infrastructure/capacity development – Five computers, two printers, an office table and a UPS power saver were purchased. Regarding IT infrastructure, a server as well as the internet connection (parabolic reflector) has been installed in Fougamou. A second office (for receiving study protocols) has been established in Libreville. The maintenance and upgrade of the NEC's website took place: www.cner-gabon.org/cner 2. Training (resources developed (e.g. manuals) and human capacity developed) – Members of the NEC as well as representatives of the Ministry of Public Health and the Presidency of the Republic of Gabon attended a CANTAM/AMANET

	workshop on health research ethics (for Ethics Review Committees and National Regulatory Authorities) in Yaoundé, Cameroon (27 September-1 October 2010) – Two NEC members assisted with the AVAREF (WHO) meeting in September 2010 in Nairobi allowing them to exchange knowledge on vaccines and regulations with their African colleagues – In February 2011 a one-day workshop on legal aspects (writing/implementing/revising and amending laws) was held in Fougamou – From 25 to 27 May 2011 a three-day long event ('scientific days') was organised in Libreville. The first day contained an intensive training on ethics in general and ethical aspects of clinical research. More than 60 participants attended the ethics training day. The second day took place at the national broadcasting agency (RTG) and was organised as a panel discussion. The third day took place at the two main universities of the country: Université de Sciences de la Santé and Université Omar Bongo aiming at developing an ethics curriculum for both universities. An ethics curriculum will be implemented at the Université de Sciences de la Santé. The curriculum will be mandatory for students of the following subjects: medicine, philosophy, biology and law – Training of ethics committee members and regulatory authorities' representatives, offered by UNESCO via the EDCTP project on 'assistance of bioethics communities', held in Libreville (23 to 27 July 2012; 20 participants) – Internal training of the NEC's members by the President of the NEC on the human genome research question in Gabon and in Africa (6 to 7 April 2012; 13 participants) – Scientific seminar of the Moyen-Ogouée at the Albert Schweitzer Hospital (5 May 2012; 24 participants). 3. Networking/collaborations developed **National institutions:** – Ministry of Public Health – Ministry of Research and Science – Université des Sciences de la Santé (Libreville) – Université Omar Bongo (Libreville) – Medical Research Unit, Albert Schweitzer Hospital Lambaréné – International Centre of Medical Research of Franceville – Comité d'Ethique Régional Indépendant de Lambaréné – L'Union **International institutions:** – United Nations Educational, Scientific and Cultural Organization (UNESCO) – World Health Organization (WHO) – Ethics Committee of the Chantal Biya International Reference Centre for Research on HIV/AIDS Prevention and Management (CIRCB) (Cameroon) – Comitéd'Ethique de la Recherche en Sciences de la Santé (CERSSA) (Republic of Congo) – Comitéd'Éthique National de Burkina Faso (Burkina Faso) – Ethics Committee, Medical University Vienna (Austria) – Comité International de Bioéthique (France)

	– Faculty of Law, University of Fribourg and Neuchâtel (Switzerland) – Vienna School of Clinical Research (VSCR) (Austria) – National Ethics Committee of Cote d'Ivoire – Ethics Committee of Health in Benin

1.1.37 KOLLIE-Liberia-Ethics

EDCTP Project Coordinator:	James Kollie (University of Liberia)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Strengthening the capacity of UL-PIRE IRB (University of Liberia Pacific Institute for Research and Evaluation Institutional Review Board)
EDCTP Project Code:	CB.2009.41302.020
EDCTP Project Start Date:	13 April 2010
EDCTP Project End Date:	12 April 2012
Collaborators:	• Cecelia Morris (Liberia) • Robert Draper (Liberia) • Ellen George-Williams (Liberia) • Jemee Tegli (Liberia)
Type of Project:	Institutional Review Board
Goal:	The University of Liberia (UL) Institutional Review Board (IRB) was established in 2005 through a collaborative agreement between the Pacific Institute for Research and Evaluation (PIRE), based in the United States, and UL for the purpose of protecting human subjects and maintaining the conduct of scientific research in ethical standards in post-conflict, resource-constrained Liberia. This project was designed to address potential IRB-related challenges in post-conflict, resource-constrained settings like Liberia. UL-PIRE IRB is the only IRB presently operating in the country.
Objectives:	1. Increase and build the capacity of the UL-IRB 2. Introduce the UL deans, coordinators, researchers to human research ethics 3. Appraise the ethical knowledge of the UL graduate and professional programmes.
Status:	Completed
Results and Outcomes:	1. Infrastructure/capacity development – Two laptop computers, one desktop computer, one digital camera, one desk, two chairs and an overhead projector were purchased. 2. Training (resources developed (e.g. manuals) and human capacity developed) – Two-day training workshop (16-17 September 2010; 50 participants) on ethics in research involving human subjects was held. 3. Networking/collaborations developed – African Malaria Network Trust (AMANET)

1.1.38 Rulisa-KUTH-Ethics

EDCTP Project Coordinator:	Stephen Rulisa (University Central Hospital of Kigali, Rwanda)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Establishment and training of an Institutional Review Board (IRB) at the Kigali University Teaching Hospital (KUTH) to strengthen the ethical review capacities in Rwanda
EDCTP Project Code:	CB.2009.41302.008
EDCTP Project Start Date:	4 May 2010
EDCTP Project End Date:	3 November 2011
Collaborators:	• Heinrich Klech (Austria) • Christiane Druml (Austria) • Pierre-Blaise Matsiegui (Gabon)
Type of Project:	Institutional Review Board
Goal:	The current ethical review system in Rwanda consists of one single National Ethics Committee (NEC) that reviews all protocols carried out in the country. In order to cope with the increasing demand, the decision has been made to change the current system and establish Institutional Review Boards (IRBs) across the country to share the workload. However, there are limited resources, which hinder a rapid realisation of this plan. The EDCTP grant therefore provided an important impetus to speed up the re-organisation of the Rwandan ethical review system.
Objectives:	The Kigali University Teaching Hospital (KUTH) was chosen to be the first Rwandan research institution where an IRB will be established. INTERACT was in charge of organising a training course on ethics and for providing access to an online course on Good Clinical Practice (GCP). The training course was combined with a train-the-trainer where candidates were instructed in training skills so that they can put together and conduct their own training sessions. Additionally, this project aimed to analyse the current Rwandan legislation, to identify necessary changes or additions and to develop a strategy to be recommended to the Competent Authority. To ensure the success of the project, an administrative office with an employee experienced in clinical research, research ethics, capacity building and with organisational skills will be responsible for six month (part-time) administrative support and coordination of the IRB (one meeting per month) and the knowledge exchange between European and African ethics committees.
Cofunders:	University Central Hospital of Kigali
Status:	Completed
Results and Outcomes:	1. Infrastructure/capacity development – One computer, one photocopy machine, one fax machine and one lockable cupboard were purchased. 2. Training (resources developed (e.g. manuals) and human capacity developed) – Ethics committee members were trained on research methods (5–9 September 2011; 10 participants) and GCP training was held (15-16 September 2011; 20 participants) – Training on Human Subjects for the 3 IRBs (Centre Hospitalier Universitaire De Kigali [CHUK], Centre Hospitalier Universitaire de Butare [CHUB] and Kigali Health Institute [KHI]) were held (11-13 January 2012; 17 participants).

	3. Networking/collaborations developed – Centre Hospitalier Universitaire de Butare (CHUB) – Kigali Health Institute (KHI)

1.1.39 Mugyenyi-JCRC-Ethics

EDCTP Project Coordinator:	Peter Mugyenyi (Joint Clinical Research Centre (JCRC), Uganda)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Strengthening of the ethical review capacity of the Joint Clinical Research Centre (JCRC) IRB and collaborating IRBs in north and western Uganda
EDCTP Project Code:	CB.2009.41302.011
EDCTP Project Start Date:	17 May 2010
EDCTP Project End Date:	16 May 2012
Collaborators:	• Cissy Kityo (Uganda) • Jesse Kagimba (Uganda) • Jasper Ogwal Okeng (Uganda) • Ferrie Nangobi (Uganda)
Type of Project:	Institutional Review Board
Goal:	To enhance the capacity of the JCRC-IRB to oversee bioethical issues in human research.
Objectives:	1. Improving policies and Standard Operating Procedures (SOPs) for pre- and post-approval of research 2. Mentorship of Gulu University IRB Members 3. Facilitating and supporting education in biomedical research ethics related to research reviews. JCRC proposes to conduct an annual five day training course on Bioethics and Good Clinical Practice targeting JCRC-IRB members, networking IRBs in the country as well as researchers and other health scientists 4. IRB database. Develop a modern database where IRB members and researchers can get information on the JCRC-IRB activities and actions, on-going studies, status of submitted proposals, IRB members' names and contact details, SOPs and Terms of Reference. Networking of IRBs. JCRC-IRB Secretariat will host meetings and videoconference discussions of IRB members from collaborating and other IRBs in the country to discuss ethical issues/challenges, make recommendations on necessary policy changes and review progress of the project activities.
Cofunders:	Clinical Operationals and Health Services Research (COHRE) Training Program based at Joint Clinical Research Centre (Uganda)
Status:	Completed
Results and Outcomes:	1. Infrastructure/capacity development – A LCD projector, one laptop computer, one desktop computer (and accessories), one printer, one desk, one shredder, one filing cabinet and three chairs were purchased. 2. Training (resources developed (e.g. manuals) and human capacity developed) – Two Good Clinical Practice (GCP) and Research Ethics (RE) training sessions were conducted in the first year. The first workshop targeted IRB members and researchers from within Kampala, Gulu and Mbarara IRBs (1-4 November 2010; 40 participants) – The second GCP and RE training was held in Gulu in northern Uganda, targeting IRB members and researchers (2-5 May 2011; 25 participants). At the end of the two workshops, participants received a joint

	GCP and RE certificate – A 'training of trainers (TOT)' workshop as a follow-up to the GCP and RE was held (23-24 March 2011; 25 participants). In the second year, three training workshops were conducted – A 'Good Clinical Practice and research ethics and onsite support training' for Gulu University IRB members took place (9 February 2012; 30 participants) – A two day training on 'Good Clinical Practice and research ethics training' took place (7-8 May 2012; 40 participants). Participants were drawn from EDCTP partner institutions and other IRB members from institutions within Kampala – A three day 'training of trainers' workshop took place (9-11 May 2012; 40 participants). Participants were purposively selected personnel that had been previously trained in GCP and research ethics and these included IRB members from JCRC, Gulu University and Mbarara University as well as other collaborating IRC members. SOPs for the JCRC-IRB were developed and are being used by other collaborating IRBs while they develop their own. 3. Networking/collaborations developed – Center for Social Science Research (CeSSRA), United States – Uganda National Council for Science and Technology (UNCST) – Strategic Initiative for Development of Capacity in Ethical Review (SIDCER) – Gulu University – Mbarara University of Science and Technology (MUST) – Mukono University – Mildmay Uganda – Uganda Virus Research Institute (UVRI) – Makerere University – The Aids Support Organization (TASO) – Nsambya Hospital IRB – Ndejje University – Infectious Disease Institute Uganda – Makerere University John Hopkins Collaboration (MUJHU Research Collaboration)

1.1.40 Gaie (Ndebele)-Botswana-Ethics

EDCTP Project Coordinator:	Joseph Balatedi Radinkudikae Gaie (University of Botswana)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Strengthening of the University of Botswana IRB and establishment of the UB Research Integrity Office
EDCTP Project Code:	CB.2010.41302.020
EDCTP Project Start Date:	21 March 2011
EDCTP Project End Date:	20 September 2013
Collaborators:	• Mike Kachedwa (Malawi) • Mary Kasule (Botswana) • Isaac Mazonde (Botswana) • Rosemary Musesengwa (Zimbabwe)
Type of Project:	Institutional Review Board
Goal:	The project aims to ensure that studies conducted by University of Botswana (UB) staff and students conform to internationally accepted standards. In addition, the project will ensure that the UB Institutional Review Board (IRB) plays a more central role in coordinating human research and is in a better position to respond to both national and international challenges in research oversight.
Objectives:	The main objective is to strengthen UB's IRB so as to enhance its capacity in research oversight, ethical review and monitoring of research conducted by UB staff, students and affiliates. The project will ultimately contribute towards the independence, competence and transparency of the UB IRB. To address this objective, the project will include five components: 1. Enhancing the ethical review and monitoring of studies conducted by UB staff, students and affiliates 2. Streamline the clearance of research and the issuing of research permits by government ministries 3. Setting up the IRB Office, including hiring an IRB assistant and purchasing relevant equipment necessary for the smooth functioning of the IRB Office 4. Developing Standard Operating Procedures for the IRB 5. Sensitising UB staff, students and affiliates in research ethics and integrity through various ways.
Status:	Ongoing
Results and Outcomes:	1. Infrastructure/capacity development – The IRB office was set up and the following equipment was purchased: one desktop computer, one printer, one laptop, one shredder and one hard drive. The post of IRB administrator was created and the position filled. 2. Training (resources developed (e.g. manuals) and human capacity developed) – SOPs and guidelines on human research were developed during the IRB Workshop (21-22 October 2011; 16 participants) – Seminar on 'Fundamentals of research ethics' was held for graduate students (28 October 2011; 11 participants) – Seminar on 'Informed consent in research with humans' was held for UB staff (13 September 2011; 12 participants) – Two IRB members attended a workshop in South Africa (4-5 August 2011) on 'Fundamentals of research ethics' organised by the Tshwane University of Technology and

	SARIMA – Two IRB members attended the African Administrators Research Ethics Conference in Botswana (26-27 September 2011). 3. Networking/collaborations developed – National Health Research Development Committee – Mapping African Research Ethics and Drug Regulatory Capacity (MARC)

1.1.41 Kaptue-Cameroon-Ethics

EDCTP Project Coordinator:	Lazare Kaptue (Cameroon National Ethics Committee (CNEC), Cameroon)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Strengthening the Cameroon National Ethics Review Committee
EDCTP Project Code:	CB.2010.41302.008
EDCTP Project Start Date:	11 April 2011
EDCTP Project End Date:	10 April 2013
Collaborators:	• Jérôme Ateudjieu (Cameroon) • Ogobara Doumbo (Mali) • Sylvie Hansel-Esteller (France) • Marceline Djuidje Ngounoue (Cameroon) • Dominique Sprumont (Switzerland) • Jonas Tchakoa (Cameroon) • Timoléon Tchuinkam (Cameroon)
Type of Project:	National Ethics Committee
Goal:	EDCTP support to the CNEC (Cameroon National Ethics Review Committee) will be used to achieve CNEC's priorities expecting to sustainably improve its transparency, independency, and effectiveness during protocols evaluation and to promote the development of cooperation and communication between the CNEC local and regional committees. In addition, it will help strengthen through the CNEC collaboration with local partners, other African National Research Ethics Committees and with international partners like the TRREE for Africa project, The Volkswagen Foundation; north–south and south-south network of ethical review to contribute in ensuring the highest competence in biomedical research.
Objectives:	This project will support the CNEC in strengthening its capacity in reviewing research protocols by: 1. Updating Standard Operating Procedures (SOPs) for protocol review and monitoring, and contribute to the harmonisation of SOPs of other ethics committees in Cameroon 2. Ensuring on-going training of its members in protocol evaluation, site visits monitoring and follow-up of protocols implementation 3. Improving access to infrastructure for its activities 4. Improving the condition of protocols and informed consent evaluation and follow-up 5. Organising training at the university level 6. Organising workshop for investigators.
Cofunders:	Cameroon National Ethics Committee for Human Health Research
Status:	Ongoing
Results and Outcomes:	1. Infrastructure/capacity development – One laptop, one desktop, one photocopier, one printer, one video projector, one projection screen, one camera, one table, twelve chairs, a filling cabinet and a desk were purchased. A website for the Cameroon National Ethics Committee is in development. 2. Training (resources developed (e.g. manuals) and human capacity developed) Six training sessions on health research ethics took place: – 1 June 2011: Banganté (49 participants) – 28 July 2011: Yaoundé (52 participants)

	– 31 August – 01 September 2011: Workshop for investigators - Yaoundé (65 participants) – 27 January 2012: University of Dschanq (51 participants) – 7 February 2012: Douala (17 participants) – 8 February 2012: University of Buea (35 participants) – Workshop on “Harmonisation of SOPs” for Research Ethics Committees (RECs) took place in Yaoundé (27-29 June 2012; 25 participants). SOPs for Cameroon National Ethics Committee were drafted and proposed to the new committee. Twenty protocols including five clinical trials and 12 multi-country studies have so far been monitored in 15 different institutions in four out of 10 health regions/towns in Cameroon including Centre (Yaounde), Littoral (Douala), West (Dschang) and South west (Kumba). 3. Networking/collaborations developed – Training Resources in Research Ethics Evaluation (TRREE) – Chaire de droit de la santé, University of Neuchatel, Switzerland – Comité de Protection des personnes, Montpellier, France – University of Yaoundé I – University of Dschang – University of Buea – University des Montagnes – University of Bamenda

1.1.42 Woldeamanuel (Petros)-ETBIN-2-Ethics

EDCTP Project Coordinator:	Yimtubezinash Woldeamanuel
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Establishing and strengthening health research ethics committees in Ethiopia
EDCTP Project Code:	CB.2010.41302.014
EDCTP Project Start Date:	20 April 2011
EDCTP Project End Date:	19 October 2013
Collaborators:	• Abraham Aseffa (Ethiopia) • Fisseha Haile Meskal (Ethiopia)
Type of Project:	National Ethics Committee, Institutional Review Board
Goal:	This project is a continuation of the Ethiopian Bioethics Initiative (ETBIN's) EDCTP supported project towards establishing and strengthening IRBs in Ethiopia.
Objectives:	1. Assist with the formation of new IRBs and build their capacity, including helping establish IRBs in the seven new universities identified, training members of the new IRBs, and providing material support to the new IRBs 2. Monitor and provide professional support to the IRBs that were formed through the previous EDCTP supported ETBIN project as well as train new members appointed/elected to existing IRBs 3. Translate the ethics booklet written in Amharic (with EDCTP support) into at least two more Ethiopian languages, thus contributing to much broader awareness creation 4. Strengthen the ETBIN office (office space, equipment and reference materials) to enable it not only to manage projects, but also develop and sustain an effective network of IRCs 5. Organise ETBIN's General Assembly to enhance its organisational capacity 6. Provide administrative support to organising PABIN's General Assembly.
Cofunders:	Armauer Hansen Research Institute (AHRI)
Status:	Ongoing
Results and Outcomes:	1. Training (resources developed (e.g. manuals) and human capacity developed) – The process of assisting the formation of new IRBs started with a needs assessment and awareness creation visits to five newly established universities followed by a five day bioethics training (Human Subject Protection, GCP, SOP development; 5-9 September 2011; 40 participants) workshop for the newly formed IRB members from the universities. The training is based on a standard curriculum, recognised by SIDCER/WHO. The following are the beneficiary institutions: • Adama University • Jijiga University • Wollo University • Nekemt University • Debre Birhan University – Strengthening existing IRBs: one newly appointed member, who has no basic training in bioethics, from each of the institutions with an already existing IRB

	was also included in the five day training workshop that was given to the IRB members of the new universities. The following institutions benefitted from this training: Gondar University; Aklilu Lemma Institute of Pathobiology, AAU; Wollega University; Armauer Hansen Research Institute (AHRI/ALERT); Arbaminch University; Mekele University; Haramaya University; Bahir Dar University; Hawassa University; and National Ethics Committee. – A 35-page Health Research Popularization Booklet, which was prepared in Amharic (national language) with funding through the previous EDCTP project to ETBIN, has been translated into two other major languages in Ethiopia (Tigrigna and Afan Oromo) and is ready for publication. 2. Networking/collaborations developed – Adama University – Jijiga University – Wollo University – Nekemt University – Debre Birhan University

1.1.43 Yevoo-Ghana-Ethics

EDCTP Project Coordinator:	Lucy Yevoo (Dodowa Health Research Centre, Ghana)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Establishment and strengthening the activities of the Dodowa Health Research Centre's Institutional Review Board
EDCTP Project Code:	CB.2010.41302.015
EDCTP Project Start Date:	11 April 2011
EDCTP Project End Date:	10 April 2013
Collaborators:	• Sheila Addei (Ghana) • Okyere Boateng (Ghana) • Margaret Gyapong (Ghana) • John Gyapong (Ghana) • Raymond Aborigo (Ghana)
Type of Project:	Institutional Review Board
Goal:	The Dodowa Health Research Centre (DHRC) is one of the three research institutions within the Ministry of Health (MOH) and the Ghana Health Service (GHS) mandated to conduct research that contributes to the improvement of the health status of the people of Ghana. Currently, the centre does not have a permanent Institutional Review Board (IRB).This project aims to establish and strengthen the activities of an IRB for the DHRC.
Objectives:	1. Establish an Ethical Review Board for the Dodowa Health Research Centre 2. Develop Standard Operating Procedures (SOPs) for the IRB 3. Promote networking and sharing of ideas among IRB members and researchers to ensure high standards 4. Train ethics review board members 5. Catalogue protocols 6. Educate community members about their ethics rights in research activities 7. Establish institutional structures and communication strategies for the IRB 8. Set up field monitoring processes by committee members for on-going research.
Cofunders:	Dodowa Health Research Centre (DHRC)
Status:	Ongoing
Results and Outcomes:	1. Infrastructure/capacity development – One desktop computer and accessories, one lap top, one paper shredder, one photocopier, one printer, one projector, one UPS stabiliser, one cabinet and one scanner were purchased. 2. Training (resources developed (e.g. manuals) and human capacity developed) – Terms of reference and operational guidelines for the IRB were developed. A schedule for IRB meetings has been published (the Board meets quarterly). Two workshops took place: • Historical development of ethics and the aims, objective and importance of an IRB (28 June 2011; 14 participants) • Informed consent and reviewing a protocol (13 September 2011; 17 participants). 3. Networking/collaborations developed – Noguchi Memorial Institute of Medical Research (NMIMR) – Research and Development Division, Ghana Health

	Service (RDD) – Georgetown University – Copenhagen Sustainable Sanitation (SUSA) Project – Institute of Infectious Diseases of Poverty – Centre for Disease Control and the School of Public Health, School of Allied Sciences, University of Ghana

1.1.44 Bhatt-Kenya-Ethics

EDCTP Project Coordinator:	Kirana Bhatt (University of Nairobi, Kenya)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Strengthening of National Ethics Research Committees, networking and capacity building in Kenya
EDCTP Project Code:	CB.2010.41302.024
EDCTP Project Start Date:	15 April 2011
EDCTP Project End Date:	14 April 2012
Collaborators:	• Anastasia Guantai (Kenya) • Christine Kigondu (Kenya) • Micah Oyaro (Kenya) • Simon Lang'at (Kenya)
Type of Project:	National Ethics Committee
Goal:	This project aimed at improving the efficiency and expansion of Ethical Research Committees (ERC) in Kenya.
Objectives:	An inventory of all ethics review committees was taken. It also expanded its functional capacity through purchase of new office equipment (computers, printers, projectors and photocopiers), training of ERC members on bioethics, networking with local and external ERCs (north to south, south to south) to enhance ethical review processes in single and multi-clinical projects in Africa where the burden of infections is high. To improve the efficiency and functional capacity, a well-structured questionnaire was designed to take inventory of various ethics committees in Kenya, their location, facilities and composition of its members. The study also identified the gaps and challenges. It is anticipated that the turnaround time for ethical review process will reduce by half, 100% composition of all ERCs in Kenya will be known, more than 90% of all ERCs represented in the project will receive all the necessary Standard Operating Procedures (SOPs), including the other relevant information. In addition, a long-term sustainability plan was established through joint collaborations to ensure continuous updating of ethical review research activities through the websites and monitoring of the various ERCs activities under the National Council of Science and Technology, which is the governing body of all research in Kenya.
Status:	Completed
Results and Outcomes:	1. Infrastructure/capacity development – One laptop, three desktop computers, one LCD projector, one photocopier, two printers and one scanner were purchased. The website was upgraded and a database for capturing data relating to research activities was created. 2. Training (resources developed (e.g. manuals) and human capacity developed) – A three-day workshop on "Ethics and research" took place (15-18 January 2012; 58 participants) – A second follow-up workshop was held to review progress and assess the immediate benefits of the ethics workshop (18 May 2012; 36 participants). An inventory of all ethics review committees in Kenya was undertaken in collaboration with the National Council for Science and Technology (NCST). A needs assessment was carried out countrywide to identify the existing ERCs and institutions in the process of

	establishing their own ERCs in Kenya in consultation with the NCST. A draft strategic plan was formulated through this grant, which was used as the key resource document by the University of Nairobi and Kenyatta National Hospital in the formulation of the final version of the strategic plan. A database was created and data entry is ongoing. 3. Networking/collaborations developed – Gertrude's Children's Hospital – Kenyatta University – Jomo Kenyatta University of Agriculture and Technology – Coast Provincial General Hospital – AMREF – ICIPE – Pwani University – Mombasa Polytechnic University College – Great Lakes University of Kisumu – Moi University – University of Eastern Africa – Baraton – Catholic University of East Africa – ThePresbyterian University of East Africa – Kakamega Provincial General Hospital – New Nyanza Provincial General Hospital – MasindeMuliro University of Science and Technology – Maseno University – Kijabe Hospital – Chuka University College – Kenya Methodist University – Nairobi Hospital – NationalCouncil for Science and Technology (NCST) – Kenya Medical Research Institute (KEMRI) – Aga Khan University Hospital

1.1.45 Bukusi-Kenya-Ethics

EDCTP Project Coordinator:	Elizabeth Anne Bukusi (Kenya Medical Research Institute (KEMRI), Kenya)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	ADILI – The KEMRI Bioethics Centre
EDCTP Project Code:	CB.2010.41302.016
EDCTP Project Start Date:	21 March 2011
EDCTP Project End Date:	20 March 2014
Collaborators:	• Caroline Kithinji (Kenya) • Gerald Mkoji (Kenya) • Sammy Njenga (Kenya) • Christine Wasunna (Kenya)
Type of Project:	Institutional Review Board
Goal:	This project seeks to set up the ADILI Bioethics Centre at Kenya Medical Research Institute (KEMRI) to build capacity in ethics training for both members of the ethics review committees and for investigators at the institute.
Objectives:	The aim is to establish an independent bioethics unit at KEMRI and ensure that it is appropriately staffed, trained, resourced, and entrenched within KEMRI's structures to oversee the ethical review process at the institute. To achieve this, consensus will first be built and a proposal developed (board paper) to submit to the KEMRI board of management seeking to establish the bioethics unit. Upon receiving the board's approval, training of the current Institutional Review Board (IRB) members will be initiated and a new review structure will be piloted consisting of multiple committees, which when fully established will form a fully-fledged multi-committee model in which several committees will work simultaneously to review protocols. Reviewers will be trained to conduct specialised review of highly complex protocols. To expedite and improve efficiency, an electronic review system for submission of protocols will be set up. The independent unit will provide bioethics training to scientists within KEMRI, including the graduate students, and it will establish review guidelines for the committees.
Cofunders:	• US National Institute of Health through the University of California San Francisco • US National Institute of Health through the University of Cape Town
Status:	Ongoing
Results and Outcomes:	1. Infrastructure/capacity development – Six computers, one laptop, one LCD projector, one printer, one scanner and a server were purchased. The purchase of computers and server have aided in the development of the online protocol management and tracking system (www.kemri.org/ssc). 2. Training (resources developed (e.g. manuals) and human capacity developed) – A one-day training for ethics review committee members took place (19 December 2011; 18 participants). The training included presentations on handling protocol deviation and violation. Three ethics review committee members attended a short course on bioethics (20-24 February 2012). Staff received training via online programmes, namely AMANET and the Collaborative Institutional Training Initiative (CITI).

	New forms for submission and review of protocols were developed. The task force and ERC secretariat members jointly conducted centre-level informed consent training sessions for Centre Scientific committee members at all of the 11 KEMRI centres. 3. Networking/collaborations developed – Uganda National Council for Science and Technology (UNCST) – University of Nairobi/Kenyatta National Hospital (UoN/KNH) Ethics Research Committee – National Council of Science and Technology (Kenya)

1.1.46 Otieno-Kenya-Ethics

EDCTP Project Coordinator:	Wellington Otieno (Centre for Research and Technology Development (RESTECH), Kenya)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Establishment of Institutional Research and Ethics Committee (IREC) in Western Kenya
EDCTP Project Code:	CB.2010.41302.025
EDCTP Project Start Date:	3 March 2011
EDCTP Project End Date:	2 June 2013
Collaborators:	• Kawango Agot (Kenya) • Erick Nyambedha (Kenya) • Wilson Odero (Kenya) • Spala Ohaga (Kenya)
Type of Project:	Institutional Review Board
Goal:	The Centre for Research and Technology Development (RESTECH) was established in 2007 and is located in Kisumu City in Nyanza Province, Western Kenya. Currently, research institutions and universities in Western Kenya do not have an ethics review committee. Ethical approval of all research proposals developed by staff and postgraduate students at universities and research organisations in Western Kenya can only seek ethics approval from one of the three local IRBs (Kenyatta National Hospital/University of Nairobi Research and Ethics Committee (KNH-ERC), Kenya Medical Research Institute Institutional Review Board (KEMRI IRB), and Moi University Institutional Research and Ethics Committee (IREC)). Researchers from Western Kenya institutions often obtain ethical approval from KNH-ERC or KEMRI-IRB, yet given the close geographical proximity of RESTECH to the research sites, it would be more appropriate to receive approval and ethical oversight from the proposed IREC to be based at RESTECH in Kisumu to serve the local needs of the researchers.
Objectives:	1. Increase awareness and appreciation for the ethical approval process and oversight in the conduct of research, as well as the uptake of ethical review services among university academic staff, National Research Institute, NGOs and students 2. Establish a functional Institutional Research and Ethics Committee (IREC) at the RESTECH Centre, with the capacity to review biomedical and social science research proposals and provide ongoing ethical oversight to studies conducted by or in collaboration with the universities and the National Research Institutes within the region 3. Design strategies to ensure technical and financial sustainability of the Institutional Research Ethics Committee for Western Kenya (WK-IREC).
Cofunders:	• Maseno University (Kenya) • Centre for Research and Technology Development (RESTECH) (Kenya) • Impact Research and Development Organization (Impact-RDO) (Kenya)
Status:	Ongoing
Results and Outcomes:	1. Infrastructure/capacity development – Two computers and two printers were purchased. 2. Training (resources developed (e.g. manuals) and human capacity developed)

	– A training workshop for postgraduate students on ethics was held over two days (9-10 November 2011; 20 participants). A website for the REC is under construction. A Local Area Network (LAN) has been developed linking the researchers and project staff at RESTECH. Two members of staff have been given short-term training (16-22 April 2011) on principles and practices on Institutional Research Ethics Committee operations by an external consultant. The following documents have been developed: • Ethics Review Committee guidelines for Standard Operating Procedures (SOPs) • Application form for ethics review • Ethics review evaluation form • Information sheet/consent form. 3. Networking/collaborations developed – University of Boston School of Public Health – International Centre of Insect Physiology and Ecology (ICIPE) – South African Research and Ethics Committee (SAREC) – London School of Hygiene and Tropical Medicine – African Malaria Network Trust (AMANET)

1.1.47 Manda-Malawi-Ethics

EDCTP Project Coordinator:	Lucinda Manda-Taylor (University of Malawi)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Enhancing community understanding and participation in human subjects protection in Malawi
EDCTP Project Code:	CB.2010.41302.012
EDCTP Project Start Date:	31 March 2011
EDCTP Project End Date:	30 March 2013
Collaborators:	• Tamara Chipasula (Malawi) • Linda Kalialani-Phiri (Malawi) • Joseph Mfutso-Bengo (Malawi) • Victor Mwapasa (Malawi)
Type of Project:	Institutional Review Board
Goal:	The aim of this project is to build the capacity of local researchers and research participants.
Objectives:	1. Enhancing understanding of the research community in Malawi, which includes researchers within and out of the College, faculty and students, on human subject's protection in research. This will improve human subject's protection compliance from proposal development through to implementation, and therefore also strengthen Good Clinical Practice and regulatory compliance in clinical research 2. Enhancing knowledge and understanding of communities (research participants) on matters of human subject's protection. This will have several positive benefits to research, including improving the informed consent process, improved protection of research participants and possibly improved study recruitment and compliance 3. Firstly, the aim is to develop and/or adapt a course on human subject protection that will be offered to the research community in Malawi. Secondly, the aim is to develop/adapt human subject's protection course for research participants in and around villages near clinical research sites and establish and train Community Advisory Boards (CABs) at sites where CABs are absent. These objectives contribute to the overall function of and will be guided by COMREC (College of Medicine's Research and Ethics Committee) and informed by local and international research ethics and regulatory guidelines.
Status:	Ongoing
Results and Outcomes:	1. Infrastructure/capacity development – One laptop was purchased. 2. Training (resources developed (e.g. manuals) and human capacity developed) – A three day course in Human Subject's Protection took place (6-8 June 2011; 25 participants). – A three day course in Human Subject's Protection and Community Advisory Boards (CAB) took place in Mpemba (11-13 July 2011; 36 participants). Thereafter, a CAB was established in the community that was linked to a clinical trial site taking place at the health centre in the area. – A three day course in Human Subject's Protection and Community Advisory Boards (CAB) took place in Madziabango (21-24 September 2011; 29

	participants). Thereafter, a CAB was established in the community that was linked to a clinical trial site taking place at the health centre in the area. – A three day course in Human Subject's Protection and Community Advisory Boards (CAB) took place in Thyolo (26-28 January 2012; 40 participants). Thereafter, a CAB was established in the community that was linked to a clinical trial site taking place at the health centre in the area. – All community engagement training activities were preceded by a sensitisation workshop where community leaders and local health surveillance officers were invited and informed about the objectives of the training. 3. Networking/collaborations developed – National Commission for Science and Technology (Malawi) – Pharmacy, Medicines and Poisons Board (PMPB) (Malawi) – Medical Research Council of Zimbabwe (MRCZ)

1.1.48 Otuonye-NIMR-Ethics

EDCTP Project Coordinator:	Ngozi Otuonye (Nigerian Institute of Medical Research, Nigeria)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Establishment of RECs and capacity building of human resources and infrastructure in Nigeria
EDCTP Project Code:	CB.2010.41302.027
EDCTP Project Start Date:	11 April 2011
EDCTP Project End Date:	10 October 2012
Collaborators:	• Nwaokorie Franka (Nigeria) • Dominique Sprumont (Switzerland) • Tinto Halidou (Burkina Faso)
Type of Project:	Institutional Review Board
Goal:	This project improved the capacity of health personnel (doctors, nurses, medical laboratory scientists, pharmacists, clergies, lawyers, community representatives and research scientists) to effectively conduct ethically sound research that is of international standard. HRECs were established at Mainland Hospital Yaba (MHY) and Ambrose Ali University (AAU). Their infrastructure was strengthened to improve the administrative capacity and efficiency of the HRECs.
Objectives:	This project established competent, operational and independent HRECs that will protect the wellbeing of participants, especially highly vulnerable groups. In addition, the infrastructural capacity was strengthened to improve the HREC administrators' capacity. This enables them to understand the operations of a research ethics committee and how to adequately review research protocols and monitor research. The newly elected HREC members from the two institutions (AAU and MHY) were mentored by NIMR IRB in collaboration with NHREC and NHVMAS. This was to facilitate the conduct of ethical research in practice at their various sites.
Status:	Completed
Results and Outcomes:	1. Infrastructure/capacity development - The HREC offices at MHY and AAU were equipped with the following: two air conditioners, two tables, six chairs, two photocopiers, two printers, two scanners, two computers, two fridges, two filing cabinets, two UPS and two fans. A one year internet subscription was purchased for MHY and AAU. 2. Training (resources developed (e.g. manuals) and human capacity developed) - Research ethics training modules were prepared and endorsed by the NHREC. Health personnel and researchers received training on ethics (GCP, research ethics guidelines, research monitoring, informed consent): MHY (28 June-1 July 2011; 69 participants) and AAU (18-21 October 2011; 42 participants). HREC members were appointed in line with the NHREC guidelines. The NHREC inaugurated the elected HREC members from MHY (11 member committee) and AAU (15 member committee). Mentorship training on operationalising IRB and research monitoring (14-16 August 2012; 27 participants from MHY, AAU and NIMR IRB). The mentorship programme covered organisation/administration of the IRB secretariat, procedures/conduct of IRB meetings, and monitoring of

	research programmes. Participants were registered to conduct online training in research ethics through the following programmes: TRREE and AMANET. 3. Networking/collaborations developed – New HIV Vaccine and Microbide Advocacy Society (NHVMAS) – Nigerian Institute of Medical Research IRB (NIMR IRB) – African Malaria Network Trust (AMANET) – Training and Resources in Research Ethics Evaluation for Africa (TRREE) – West African Bioethics Training Programme (WAB) – University of Neuchâtel – Centre Muraz (Burkina Faso)

1.1.49 Oyedeji-NIMR-Ethics

EDCTP Project Coordinator:	Kolawole Solomon Oyedeji (Nigerian Institute of Medical Research, Nigeria)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Capacity building and support for three ethics review committees in North Central and South Western geopolitical zones of Nigeria
EDCTP Project Code:	CB.2010.41302.022
EDCTP Project Start Date:	11 April 2011
EDCTP Project End Date:	28 February 2013
Collaborators:	• Timothy Abolarinwa (Nigeria) • Johnson David (Nigeria) • Oliver Ezechi (Nigeria) • Morenike Ukpong (Nigeria)
Type of Project:	Institutional Review Board
Goal:	This project aims to provide some basic support and training for three ethics review committees in two geopolitical zones in Nigeria, namely North Central and South Western.
Objectives:	1. Organise a training workshop for ethics review committee members of the University of Ilorin Teaching Hospital, Ladoke Akintola University Teaching Hospital and Olabisi Onabanjo University Teaching Hospitals on protocol review and providing constructive feedback, research monitoring and the use of PRO-IRB software 2. Support institutional capacity building for these three ethics review committees through the purchase and installation of basic computer hardware and software. This will enable each ethics review committee to ensure improved Secretariat performance through proper record keeping and access to continuing education training and re-training of the ethics review committee members 3. Provide a platform for networking, collaboration and promote discussion on contemporary issues and dilemmas of health research ethics among these ethics review committees and other local and national ethics committees through communication via internet based fora.
Status:	Completed
Results and Outcomes:	1. Infrastructure/capacity development – Three printers, three UPS, three desktop computers, three modems, one laptop and one projector were purchased. The three ethics committees therefore received full computer systems and internet connectivity. 2. Training (resources developed (e.g. manuals) and human capacity developed) – The Nigerian Institute of Medical Research (NIMR) organised a five day training session for members of the three ethics committees (UITH: 18-22 July 2011, 30 participants; LAUTECHTH: 5-9 September 2011, 27 participants; OOUTH: 1-5 December 2011, 40 participants) on how to review a protocol and provide constructive feedback. The programme also provided training on the use of PRO-IRB computer software for record keeping and documentation of the protocol review process in the respective ethics committees. The training was accredited by the NHREC with

	accreditation number: NHREC training certificate No. NHREC/TR/15/07/2011 according to the National Code on Health Research Ethics (NCHRE) in the country. 3. Networking/collaborations developed – South African Research Ethics Training Initiative (SARETI) – West African Bioethics Training Programme (WABTP)

1.1.50 Kruger-SAREN-Ethics

EDCTP Project Coordinator:	Mariana Kruger (Stellenbosch University, South Africa)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Network of Southern Africa Research Ethics Committee (REC) Chairpersons and development of a review textbook for African REC members (SAREN – South African Research Ethics Network)
EDCTP Project Code:	CB.2010.41302.010
EDCTP Project Start Date:	21 March 2011
EDCTP Project End Date:	20 December 2013
Collaborators:	• Phil Hans-Jörg Ehni (Germany) • Lyn Horn (South Africa) • Urban Wiesing (Germany)
Type of Project:	Coordination function
Goal:	This project will enable the chairs of ethics review committees as well as other leaders in the field of research ethics in Africa to identify and explore the current issues in ethics review. The exploration of these concepts will be used as the basis for an African textbook of ethics review to assist African ethics review members in their important task of protecting research participants.
Objectives:	The first objective of this project is to establish a network of Chairpersons of sub-Saharan Research Ethics Committees. The starting point of this network will be to host a two or three day face to face meeting of Chairpersons of sub-Saharan and Southern Africa and other REC members in order to identify and discuss common problems and challenges. The second purpose of this meeting will be to initiate and identify a steering committee that will plan and write a detailed review textbook for African IRBs similar in part to the Institutional Review Board: Member Handbook by Robert J. Amdur and Elizabeth A. Bankert (Jones & Bartlette Publishers), now in its third edition and used extensively by IRB members in the USA and Canada. The second phase of the project, after the 'Forum of Chairpersons' meeting, will be the writing of the textbook and the development of a sustainable online REC discussion forum and blog.
Status:	Ongoing
Results and Outcomes:	1. Training (resources developed (e.g. manuals) and human capacity developed) – A workshop for African REC Chairs, members and administrators to discuss health care research issues in Africa and to plan for the textbook was held (12–13 August 2011). 2. Networking/collaborations developed – Mapping African Research Ethics and Drug Regulatory Capacity (MARC) – University of Ghana – Cameroon National Ethics Committee – Kenya Medical Research Institute (KEMRI) – Medical Research Council Zimbabwe (MRCZ) – St John's University (Tanzania) – Biomedical Research and Training Institute (BRTI) – Walter Sisulu University – CERMES – Medical Research Institute (Egypt) – University of Liberia

	– Ministry of Defence (Nigeria) – University of Zimbabwe

1.1.51 Msambichaka-Tanzania-Ethics

EDCTP Project Coordinator:	Beverly Msambichaka (Ifakara Health Research and Development Centre, Tanzania)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Customisation and strengthening of the IHI-IRB capacity to regulate health research ethics
EDCTP Project Code:	CB.2010.41302.026
EDCTP Project Start Date:	3 March 2011
EDCTP Project End Date:	2 March 2013
Collaborators:	• Sherry Armstrong Wilkinson (Austria) • Abdallah Mkopi (Tanzania) • Mwifadhi Mrisho (Tanzania) • Aceme Nyika (Tanzania) • Ahmed Saumu (Tanzania)
Type of Project:	Institutional Review Board
Goal:	The IHI–IRB (Ifakara Health Institute Institutional Review Board) seeks to establish a training unit in health research ethics serving Tanzanian institutions and others in Africa.
Objectives:	1. Customise the IHI-IRB office This objective addresses the challenge of document storage to match the increasing volume of printed material. It also addresses the issue of having the facilities to accommodate a dedicated person (part-time) to take on the role of establishing and maintaining an up to date IRB database and archive. These are considered to be important challenges, taking into consideration that the IRB is expected to adhere and comply to all ethical requirements and at the same time be eligible for auditing at any time by local and international ethical authorities. 2. Establish a well-managed database and archiving system for IHI-IRB This objective assumes the responsibility of ensuring that the IRB secures a suitable candidate to take up the role of managing IRB data following a short training. It is expected, from this objective, that the IHI-IRB will be able to produce a quarterly report on general IRB performance as well as overall performance of the project. 3. Support personnel cost and IRB members allowance This objective addresses the problem of low review allowances for IRB members and responsibility allowances for members of the Secretariat. In this project the project coordinators and data manager's salaries will receive responsibility allowances. It is expected that IRB members' attendance of review meetings will continue to be maintained at not less than 70%. The responsibility allowance is a contribution towards time spent in implementing the project. 4. Promote HRE awareness among clinical trial communities This objective targets the clinical trial communities. Through public awareness activities, these communities will be able to get a better understanding of the importance of clinical trials and their valuable contribution in participation as well as the importance of HRE, the informed consent process, their rights and responsibilities. Through discussions in the seminar, we may deduce how best to enhance our IRB.

	5. Facilitate effective clinical trial oversight visits The aim is to be able to develop a platform for effective clinical trial oversight visits with a proper format for review of clinical trials that can be replicated elsewhere in similar settings. 6. Build capacity of IRB members and IHI staff on HRE The aim is to strengthen IRB members' capacity to identify relevant issues of ethical concern during review. The purpose of inviting different participants is to propagate the know-how, but at the same time to develop a common direction or approach between the NEC and IRBs in reviewing documents. From this training, NECs and IRBs should be able to develop their own protocol review guides, which in future could be harmonised across ethical bodies and thereby reduce duplication of efforts. Investigators will be trained on the informed consent process and Good Clinical Practice, while field workers will be strengthened on field HRE application skills.
Status:	Completed
Results and Outcomes:	1. Infrastructure/capacity development – One desk, one office chair and one desk top computer were purchased. 2. Training (resources developed (e.g. manuals) and human capacity developed) – An assistant data and archiving manager was recruited. This person is completing a two-year diploma on Record Management. The diploma is due to be completed in 2013. Three training sessions for IRB members and investigators took place: • Experimental designs and how it impacts on health research • ethics (10 June 2011; 12 participants) • Informed consent process (23–24 August 2011; 18 participants) • Good Clinical Practice: A step further for investigators (25–26 August 2011; 18 participants). 3. Networking/collaborations developed – African Malaria Network Trust (AMANET) – Clinical Research Africa (CRA)

1.1.52 Temu-LZIRB-Ethics

EDCTP Project Coordinator:	Mansuet Temu (National Institute for Medical Research (NIMR), Tanzania)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Strengthening the capacity of the Lake Zone Institutional Review Board (LZIRB)
EDCTP Project Code:	CB.2010.41302.006
EDCTP Project Start Date:	20 April 2011
EDCTP Project End Date:	19 April 2013
Collaborators:	• John M. Changalucha (Tanzania) • Joyce K. Ikingura (Tanzania) • Joseph R. Mwanga (Tanzania) • Mark Urassa (Tanzania)
Type of Project:	Institutional Review Board
Goal:	This project aims to strengthen the capacity of LZIRB, which was established by funds from EDCTP in 2008. Being a new organ there are many activities that need to be supported in order to make the IRB strong and independent according to the laid down guidelines. Among the activities that need financial support include training (local and international) of its members and secretariat, purchasing of equipment, furniture and supplies, top up allowance to the members of the secretariat and attendance at an ethics meeting in the country.
Objectives:	Due to limited resources in developing countries and considering the rise in the number of health researchers due to various reasons, it is justifiable to apply for funds to strengthen the capacity the local IRBs. The objectives of the project are to strengthen the LZIRB through further training of the members, train a group of protocol reviewers, train one resource person within the country, attach a secretary from within the Institute and refurbish the secretariat office. Through these activities there will be an assurance that the IRB can work properly in the protection of rights and welfare of study participants. The specific objectives are to: 1. Provide additional health research ethics training to the members of the LZIRB 2. Train and mentor a group of protocol reviewers, especially in clinical trials protocols 3. Train a resource person within the country 4. Attach a secretary and recorder from within the institute to support operations of the LZIRB office 5. Refurbish and furnish the secretariat office The intermediate steps will include: 1. Identification of a trainer who will offer continued training to the members and a group of protocol reviewers 2. Identify a person with an interest in research ethics who will be trained within the country as a resource person in research ethics 3. Identify a secretary within the institute 4. Procure furniture and other items for the secretariat office.
Status:	Ongoing
Results and Outcomes:	1. Infrastructure/capacity development – One laptop, one desktop computer, one overhead projector, one scanner, one printer, one air conditioner, three tables, four chairs and two wireless modems

	were purchased. The Secretariat office was painted and minor repairs were carried out. 2. Training (resources developed (e.g. manuals) and human capacity developed) – The workshop on “Health research ethics” took place from 28-30 November 2011 (16 participants). 3. Networking/collaborations developed – African Malaria Network Trust (AMANET) – National Health Research Ethics Committee (Tanzania) – Southern African Research Ethics Network (SAREN)

1.1.53 Birungi-TASO-Ethics

EDCTP Project Coordinator:	Josephine Birungi (The AIDS Support Organization (TASO), Uganda)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Strengthening of TASO (The AIDS Support Organization) Institutional Review Board for HIV/AIDS research in Uganda
EDCTP Project Code:	CB.2010.41302.013
EDCTP Project Start Date:	11 April 2011
EDCTP Project End Date:	10 April 2013
Collaborators:	• Shabbar Jaffar (United Kingdom) • Concepta Merry (Ireland) • Edward Mills (Canada)
Type of Project:	Institutional Review Board
Goal:	The goal of this project is to strengthen The AIDS Support Organization (TASO) Institutional Review Board (IRB) and support operational and community-based clinical HIV/AIDS research within and outside TASO.
Objectives:	1. Developing clear procedures for identifying and recruiting members of the TASO IRB 2. Reviewing and further developing TASO IRB Standard Operating Procedures (SOPs) 3. Developing a curriculum for training members of the TASO IRB and other IRBs 4. Documenting and disseminating relevant lessons learned about the establishment and strengthening of IRBs in Uganda at national and international conferences/meetings.
Status:	Ongoing
Results and Outcomes:	1. Infrastructure/capacity development – One desktop computer, one laptop, one desk, one office cabinet and one scanner were purchased. The IRB now has a furnished office with 24 hour internet services. 2. Training (resources developed (e.g. manuals) and human capacity developed) – SOPs were developed. Six planning meetings for IRB members were held. Standardised and objective tools for the review of research protocols have been developed as well as guidelines for monitoring research sites. These documents are being used by the IRB members to execute the functions of the IRB. A five day workshop in research ethics took place (16-20 May 2011; 19 participants). A two day orientation for IRB members was held (01-02 March 2012; 17 participants). Nine IRB members completed the online ethics course on “Protection of human subjects”. Eleven IRB members attended the Annual National Research Ethics Conference organised by UNCST. 3. Networking/collaborations developed – Uganda National Council for Science and Technology (UNCST) – Joint Clinical Research Centre (JCRC)

1.1.54 Zimba-Zimbabwe-Ethics

EDCTP Project Coordinator:	Moses Zimba (Harare City Health Department, Zimbabwe)
EDCTP Call Title:	Support for the Establishment and the Strengthening of African National Ethics Committees or Institutional Review Boards
EDCTP Project Title:	Establishment of an Institutional Review Board for health facilities in City of Harare
EDCTP Project Code:	CB.2010.41302.004
EDCTP Project Start Date:	15 March 2011
EDCTP Project End Date:	14 March 2012
Collaborators:	• Richard Chigerwe (Zimbabwe) • Clemence Duri (Zimbabwe) • Stanley Mungofa (Zimbabwe)
Type of Project:	Institutional Review Board
Goal:	Harare City Health Department has the mandate to review each and every research proposal accompanying applications, but the capacity to review the proposals and monitor clinical trials was limited due to inadequate knowledge and trained manpower. The goal was to establish an Institutional Review Board (IRB) for health facilities in the City of Harare.
Objectives:	The objective of this project was to establish an IRB for health facilities in the City of Harare through training 33 health workers, including doctors, nurses, pharmacists, laboratory scientists and the clergy. At the end of the project, five of the trained health workers became members of the central IRB and the other 28 became members of extension IRBs in four districts to assist the central IRB with the general monitoring of compliance by researchers in the respective health facilities as they perform their normal duties and will be drawn to fill vacancies arising in the IRB due to resignations and natural causes. Non-compliance with research ethics during project implementation is a major challenge. Researchers have the tendency to abandon the approved procedure of handling research participants, hence the need for closer monitoring. The project sought to improve the conduct of health research and ensure that proposed disease intervention clinical trials are conducted using internationally accepted standards. The project also aimed to help set up offices, procure equipment, establish a Secretariat and strengthen the capacity of the proposed IRB to review proposals with a clear understanding of study designs and implementation.
Status:	Completed
Results and Outcomes:	1. Infrastructure/capacity development – An office for the IRB was refurbished including replacement and painting of ceiling, painting of walls, door and window frames, and installation of a security screen. The office was furnished and equipped with two desk top computers, two laptop computers, one desk, five office chairs and one filing cabinet. 2. Training (resources developed (e.g. manuals) and human capacity developed) – The training manuals for the course on “Health research ethics and Good Clinical Practice” were developed and training conducted by the Medical Research Council of Zimbabwe (MRCZ). The Medicines Control Authority of Zimbabwe (MCAZ) produced the manuals and conducted the training on “Clinical trial regulation and monitoring”. The University of

	Zimbabwe conducted a course on research methodology. Three training sessions took place: – Health Research Ethics and Good Clinical Practice (04-06 May 2011; 33 participants) – Clinical Trials Regulations and Monitoring (30 June 2011; 33 participants) – Research Methodology (04-05 October 2011; 33 participants). 3. Networking/collaborations developed – Medical Research Council of Zimbabwe (MRCZ) – Medicines Control Authority of Zimbabwe (MCAZ) – University of Zimbabwe – Southern African Research Ethics Network (SAREN)

2 Regulatory Authorities

2.1.1 WHO-National (Regulatory phase 1 and 2)

EDCTP Project Coordinator:	Liliana Chocarro (WHO, Switzerland)
EDCTP Project Title:	Implementation of the "WHO programme to strengthen regulatory systems in African countries with focus on clinical trial application and inspection of clinical trials"
EDCTP Project Code:	CB.2005.20900.001
EDCTP Project Start Date:	9 June 2006
EDCTP Project End Date:	15 August 2008
Objectives:	This was a collaborative project with WHO to facilitate assessment of the national regulatory environment of various African countries and to support the development of a common regulatory framework where possible at the regional level.
Status:	Completed
Results and Outcomes:	1. Training for regulators from Botswana, Ethiopia, The Gambia, Ghana, Malawi, Nigeria, Tanzania, Uganda, Zimbabwe and Mozambique 2. Establishment of the African Regulators Forum (AVAREF) 3. Support for two AVAREF meetings and continuation of training activities of the Global Training Network Programme of WHO 4. Joint review of clinical trials involving Gabon, Kenya, Ghana, Tanzania, Mozambique, Malawi and Burkina Faso with expert support by two officials from the Belgium National Regulatory Authority.