

FERCSL NEWS

*Official Newsletter of the Forum for Ethics Review
Committees of Sri Lanka*

2014 Volume 1 Issue 1

Message from the Chairperson FERCSL



I have great pleasure in extending my warm greetings to all members via this FERCSL Newsletter. I hope this newsletter will prove to be a useful means of keeping our members informed and educated about research ethics.

The Forum for Ethical Review Committees in Sri Lanka (FERCSL) was established in 2004 at the Sri Lanka Medical Association as a means of bringing together the Ethics Review Committees (ERCs) in Sri Lanka, to the mutual benefit of each other. It was not very active initially. However, since 2007, FERCSL has become more active and organized. Currently FERCSL conducts regular training workshops on research ethics for both members of Ethics Review Committees and researchers. One of the primary aims of FERCSL is to promote the ERCs to apply for recognition under the SIDCER/FERCAP programme.

I am pleased that the long awaited FERCSL Newsletter is finally off the ground. We welcome contributions from all our members and I hope the Newsletter would be an important part of FERCSL activities.

Professor Anoja Fernando
Chairperson
FERCSL

Forum for Ethics Review Committees in Sri Lanka (FERCSL)

FERCSL is convened by the Sri Lanka Medical Association (SLMA) and is composed of member Ethics Review Committees (ERCs).

FERCSL strives to achieve these goals through the following activities:

1. Improving communication among ERCs reviewing biomedical research in the country
2. Organizing meetings and symposia
3. Stipulating Guidelines and Standard Operating Procedures for member ERCs
4. Facilitating training and education opportunities for members of ERCs in the country
5. Coordinating communication and responses on the subject of ethics review of biomedical research with WMA, WHO, UNESCO, CIOMS, and other international organizations involved in fostering ethics review.

FERCSL activities are planned and coordinated by a management committee. The management committee comprises of two members nominated by each member ERC. It is currently chaired by Prof Anoja Fernando (SLMA ERC) and the secretary is Dr Rasika Perera (FMS USJ ERC). The management committee meetings are held regularly to plan the activities of the FERCSL.

An interested ERC can become a member of FERCSL by making a written request to the Chairperson, FERCSL MC through the Head of their respective institution and nominating two members to the MC.

The Annual General Meeting of the FERCSL is held in December every year.

FERCSL helps the member ERCs to strengthen their capacity by conducting workshops to suite their individual requirements. The ERCs should contact Chairperson/Secretary FERCSL with their requests for such training.

FERCSL Activities

FERCSL conducted two workshops during the first 6 months of 2014. The topics were selected based on the needs identified at the Annual General Meeting.

A workshop for ERC members on “Conflicts of Interests and Good Clinical Practices” was held in February.

A workshop on “How to have your research proposal approved by an ERC expeditiously” was conducted in June 2014 for researchers.

Both workshops were well attended.

Write to us!



Tell FERCSL your training needs! FERCSL can organise a workshop to help your ERC.

Tell us News and Activities of your ERC that you would like to share with other ERCs and their members.

Email:fercslnews@gmail.com

Recognition of ERCs

There is no formal mechanism at present for recognition/accreditation of ERCs in Sri Lanka.

Eight ERCs have been recognised by the Ministry of Health (MoH) to grant approval for clinical trials. The requirements for recognition by the MoH can be found at:

http://cdda.gov.lk/index.php?option=com_content&view=article&id=78&Itemid=115&lang=en

Two Sri Lankan Ethics Review Committees have received recognition as having reached Strategic Initiative for Development of Capacity in Ethics Review (SIDCER) of the World Health Organisation (WHO) standards at the General Assembly of the 12th Forum for Ethical Review Committees in Asia and the Western Pacific (FERCAP) International Conference on 21 November 2012 at Waters Edge in Colombo, Sri Lanka. These are the only SIDCER recognised Ethics Review Committees in Sri Lanka.



Colombo ERC Team lead by Chairperson Prof Hemantha Senanayake and Secretary Dr Enoka Corea at the FERCAP. Colombo ERC was initially recognised in 2009 and had their recognition renewed for a further 4 years.



Sri Jayewardenepura ERC Team lead by Chairperson Dr Chandanie Wanigatunge and Secretary Dr Vathsala Jayasuriya at the FERCAP. SJP ERC received recognition for the first time.

Information on SIDCER recognition can be found at <http://www.fercap-sidcer.org/>

FERCAP SLMA NSF HUMAN SUBJECT PROTECTION COURSE

Forum for Ethical Review Committees in Asia and the Western Pacific

In Collaboration with the **Sri Lankan Medical Association**
and the
National Science Foundation of Sri Lanka

At the Board Room, Faculty of Medicine, University of Colombo, Kynsey Road,
Colombo 8
From 4 to 6 August 2014

Human Subject Protection Course

August 4, 2014

8:00-8:30	Registration	
8:30-9:00	Inauguration	
9:00-9:50	History and Overview of International Guidelines in Research Ethics (Nuremberg, Helsinki, CIOMS)	Prof. Cristina Torres
9:50-10:30	Principles of Research Ethics	Prof. Vajira H. W. Dissanayake
10:30-11:00	Break	
11:00-12:00	Ethical Issues in Clinical Research	Prof. Hemantha Senanayake
12:00-1:00	Lunch	
1:00-1:45	Ethical Issues in Epidemiological and Behavioural Research	Prof. Cristina Torres
1:45-2:30	Ethical Issues in Traditional and Alternative Medicine	Dr. Kamal Perera
2:30-3:15	Elements of Informed Consent	Dr. Chandani Wanigatunga
3:15-3:30	Break	
3:30-4:30	Case Studies	Prof. Cristina Torres
4:30-5:00	Case Presentation	

August 5, 2014

8:30-9:15	Protecting Privacy and Confidentiality of Health information	Dr. Clive James
9:15-10:00	Ethical Issues in Genetic Research	Prof. Vajira H. W. Dissanayake
10:15-10:30 Break	Break	
10:30-11:15	Addressing Vulnerability	Prof. Cristina Torres
11:15-12:00	Management of Conflicts of Interest	Prof. Vajira H. W. Dissanayake
12:00-1:00	Lunch Break	
1:00 – 2:00	Risk/Benefit Assessment in Ethical Review	Prof. Cristina Torres
2:00-3:00	Ethics in Publication	Dr. BJC Perera
3:00-3:15	Break	
3:15-4:15	Mock Review	Prof. Cristina Torres
4:15-5:00	Plenary Discussion	

August 6, 2014

8:30-9:15	Principles of Good Clinical Practice	Prof. Cristina Torres
9:15-10:00	Structure and Composition of IRBs	Dr. Malk Fernando
10:15-10:30	Break	
10:30-11:15	Review Procedures (Expedited/ Full Board)	Prof. Cristina Torres
11:15-12:00	Continuing Review	Prof. Cristina Torres
12:00-1:00	Lunch Break	
1:00 – 1:45	Serious Adverse Event Reporting	Prof. Priyadarshani Galapaththy
1:45-2:30	Documentation and Archiving	Prof. Cristina Torres
2:30-3:15	GCP Inspection and Audit	Prof. Cristina Torres
3:15-3:30	Break	
3:30-4:16	Case Studies	Prof. Cristina Torres
4:15-5:00	Plenary Discussion	

Faculty

- Prof. Christina Torres, Co-ordinator, Forum for Ethical Review Committees in Asia and the Western Pacific
- Prof. Vajira H. W. Dissanayake, Board Member, Forum for Ethical Review Committees in Asia and the Western Pacific
- Dr. Malik Fernando, Member, Ethics Review Committees of the Sri Lanka Medical Association; Faculty of Medicine, University of Colombo; and Asiri Group of Hospitals.
- Prof. Priyadarshani Galapaththy, Professor in Pharmacology and Member, Ethics Review Committee, Faculty of Medicine, University of Colombo
- Dr. Clive James, Medical Officer (Health Informatics), Ministry of Health, Sri Lanka
- Dr. Kamal Perera, Senior Lecturer and Member, Ethics Review Committee, Institute of Indigenous Medicine, University of Colombo
- Dr. BJC Perera, Joint Editor, Sri Lanka Journal of Child Health
- Prof. Hemantha Senanyake, Chairperson, Ethics Review Committee, Faculty of Medicine, University of Colombo
- Dr. Chandani Wanigathunga, Chairperson, Ethics Review Committee, Faculty of Medical Sciences, University of Sri Jayewardenepura

Register at the Sri Lanka Medical Association, 6, Wijerama Mawatha, Colombo 8

Registration Fees: Rs. 5000/-

Registration Limited to 50 Participants