

Ethics Review Committee

Faculty of Medicine University of Colombo P O Box 271, Kynsey Road, Colombo 8, Sri Lanka Telephone: +94-11-2695300 ext 240 Fax: +94-11-2691581 Email: <u>ethicscommitteemfc@gmail.com</u>

REFERENCE: EC-13-129

19th December 2013.

Dr.F.W. Refai, No 7, Mc Leod Road, Colombo 04.

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Dear Dr. Refai,

RE : Protocol No EC-13-129

Title

Efficacy and safety of thermotherapy versus Intra-lesional Sodium Stibogluconate in Cutaneous Leishmaniasis: A randomized clinical trial.

Investigators : Dr.F.W.Refai Prof. Nadira Karunaweera Prof. Rohini Fernandopulle Dr. Nayani Madarasingha

Thank you for submitting the above research proposal, which was considered by the Ethics Review Committee, at its meeting on 19.12.2013. Approval is granted to proceed.

This approval relates to the following:

- Research Proposal (Version 2.2)
- Information sheets (Version 1.1)
- Consent forms (Version 1.0)
- Data collection form (Version 1.1)



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The following members of the ERC were present at the meeting:

Dr.Panduka Karunanayake, Dr. Malik Fernando, Dr. Sriyakanthi Benaragama, Prof. Varuni de Silva, Prof.Priyadarshani Galappattthy, Prof.Ariaranee Gnanathasan, Mrs.Kumudini Hettiarachchi, Dr. Nilakshi Samaranayake, Prof. Manouri Senanayake, Dr.Jithangi Wanigasinghe, Dr.Chamari Weeraratne, Prof. Chrishantha Abeysena, Dr.Priyanga Ranasinghe, Ms.Tharindi Udulagama.

You are asked to note the following,

- This approval is valid for one year, and the committee requires that you furnish a final report.
- This approval relates to the ethical content of this study only, and you are responsible for the following:
 - Negotiating individual arrangements with the heads of service departments in those situations where the use of their resources is involved.
 - If appropriate, informing the study sponsor that the membership and procedures of the Faculty of Medicine, University of Colombo Ethics Review Committee comply with approprate guidelines of the Forum of Ethics Review Committees in Sri Lanka (FERCSL).

Yours sincerely,

Prof. Hemantha Senanayake Chairperson Ethics Review Committee Faculty of Medicine University of Colombo Ethics Keview Committer Faculty of Medicine University of Colom Kynsey Road Crìomha a