**Ethics Review Committee, Faculty of Medicine University of**

**Ruhuna**

**CONFIDENTIALITY / CONFLICT OF INTEREST AGREEMENT FORM**

In recognition of the fact, that I, …………………………………………………………………., herein referred to as the “Undersigned”, have been invited as an external reviewer of the Ethics Review Committee, Faculty of Medicine University of Ruhuna (ERC, FM, UOR), and have been asked to assess research studies involving human subjects/animal in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care according to the applied national/local regulations, institutional policies and national and international guidelines;

Whereas, the invitation of the Undersigned as an external reviewer for the ERC, FM, UOR is based on individual merit and not as an advocate or representative of a province/ territory/ community nor as the delegate of any organization or private interest;

Whereas, the fundamental duty of the external reviewer is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the Ethics Review Committee, Faculty of Medicine, University of Ruhuna, Sri Lanka must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects;

The Undersigned, an external reviewer for the Ethics Review Committee, Faculty of Medicine, University of Ruhuna, is expected to meet the same high standards of ethical behaviour to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with his/her duties as an external reviewer for the ERC, FOM, UOR. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly. As such, the Undersigned agrees to hold all Confidential or Proprietary trade secrets (“information”) in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. Written confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the ERC.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that his/her performance of this agreement is consistent with the institute’s policies and any contractual obligations they may have to third parties.

**Conflict of Interest**

It is recognised that the potential for conflict of interest will always exist, but the Faculty of Medicine, University of Ruhuna has faith in the ERC and its Chairperson to manage the conflict issues, so that the ultimate outcome is the protection of human subjects.

It is the policy of the Ethics Review Committee, Faculty of Medicine, University of Ruhuna that no external reviewer may participate in the review, recommendation or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the ERC. The Undersigned will immediately disclose to the Chairperson of Ethics Review Committee, Faculty of Medicine, University of Ruhuna any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and will abstain from any participation in discussions or recommendations in respect of such proposals, except to provide information that may be requested by the Committee.

If an applicant submitting a protocol believes that an external reviewer(s) has a potential conflict, the investigator may request that the external reviewer be excluded from the review of the protocol. The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the external reviewer(s) in question. The Committee may elect to investigate the applicant’s claim of the potential conflict.

Examples of conflict of interest cases may be any of the following:

 An external reviewer is an investigator, or a supervisor of the protocol.

An external reviewer is involved in a potentially competing research program.

An external reviewer is an employee of a drug company sponsoring the research.

Any other perceived conflict of interest, including financial.

**AGREEMENT ON CONFIDENTIALITY AND CONFLICT OF INTEREST**

In the course of my activities as an external reviewer for the ERC, FOM,UOR I may be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the Access to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as an external reviewer.

Whenever I have a conflict of interest, I shall immediately inform the Chairperson and will abstain from any participation in discussions or recommendations in respect of such proposals, except to provide information that may be requested by the Committee.

I, …………………………………………………., have read and accept the aforementioned terms

and conditions as explained in this Agreement.

 …………………………………….

**Signature of an independent external reviewer**

Date

**Signature of Chairperson**

**ERC, FM, UOR**

Date