IMPORTANT: Covering Letter to MREC

All Applications to MREC needs to be accompanied with a covering letter addressed to the Chairperson of MREC. This is a <u>formal signed</u> <u>cover letter</u> from the Principal Investigator to the MREC Chairperson. Please ensure that the list of documents stated in the covering letter is <u>complete and accurate</u> as this information will be stated in MREC approval letters. Please ensure the following details are also stated in the covering letter:

NEW APPLICATION (HAVE YET TO RECEIVE INITIAL	POST APPROVAL APPLICATION
APPROVAL BY MREC)	
 State the investigators with their roles as 	Amendment Application:
well as the sites involved.	- State purpose & type of amendment.
 If this application is based on a student's 	 List the documents to be reviewed by MREC (complete with version number and version
project, please state the name of the	date)
programme (eg. Masters in Medical Science)	- Signed by the corresponding PI or site PI
and the institute the student is affiliated to.	- CC list, relevant if you wish for the MREC decision letter to be addressed to other site PIs.
 State the study design in brief. (eg: 	NOTE: Please ensure that the amendment application form as well as the revised documents have
retrospective/ prospective study/ clinical	been uploaded in the NMRR prior to submitting to MREC.
trial, involving interviews/ questionnaires/	Annual Renewal:
archived samples/data collection from	- State the expiry date for ethical approval (based on previous MREC initial approval/
medical records/ blood collection)	annual renewal letters)
 State the targeted number of subjects/ 	- Signed by the corresponding PI or site PI
respondents in Malaysia	- CC list, relevant if you wish for the MREC decision letter to be addressed to other site PIs
 State the duration of the trial. 	NOTE: Please ensure that the annual renewal is submitted via the system at least 2 months prior
 State reasons if any waiver for consent is 	to the due date. In addition, the completed Continuing Review Form is required in this
requested.	submission.
 List the documents to be reviewed by MREC 	Study Closure/ Study termination:
(complete with version number and version	- State the expiry date for ethical approval (based on previous MREC initial approval/
date).	annual renewal letters)
 Signed by the corresponding PI or site PI. 	- Signed by the corresponding PI or site PI
- CC list, relevant if you wish for the MREC	- CC list, relevant if you wish for the MREC decision letter to be addressed to other site PIs
decision letter to be addressed to other site	NOTE: Please ensure that the Study Final Report Form/ Study Termination Memorandum and
PIs.	the covering letter are submitted via the system.