

17 June 2010

Dr Anselm Mak
Department of Medicine
National University Hospital

Dear Dr Mak,

NHG DOMAIN-SPECIFIC REVIEW BOARD (DSRB) APPROVAL

Protocol Title: Illness Perceptions and its Influence on Physical, Psychological, and Medication Compliance Outcomes in Rheumatology Patients

We are pleased to inform you that the NHG Domain Specific Review Board has approved the above research project to be conducted in National University Hospital

The documents reviewed are:

- a) IRB / DSRB Application Form: Illness Perceptions and its Influence on Physical, Psychological, and Medication Compliance Outcomes in Rheumatology Patients , **Version 1**
- b) Participant Information Sheet and Consent Form: **Version 02, dated 26 May 2010**
- c) Physician Data Collection Form : **Version 01, dated 26 May 2010**
- d) Questionnaire – Your views about your Rheumatoid Arthritis: **Version 02, dated 26 May 2010**
- e) Questionnaire – Your views about your System Lupus Erythematosus: **Version 02, dated 26 May 2010**

The DSRB acknowledges the receipt of the following documents:

- f) Questionnaire – Your views about your Rheumatoid Arthritis, Chinese: **Version 02, dated 26 May 2010**
- g) Questionnaire – Your views about your System Lupus Erythematosus, Chinese: **Version 02, dated 26 May 2010**

DSRB Ref: **E/10/228**

Please ensure that the translated copies are an accurate reflection of the original document approved by NHG DSRB.

Kindly note that the NHG DSRB accepts the authenticity of the translated copies based on the translation certificates, if any, provided by the Principal Investigator. Consequently, it is the responsibility of the Principal Investigator to ensure that the translated copies are an accurate reflection of the original approved document.

The approval period is from **17 June 2010 to 16 June 2011**. The reference number for this study is **DSRB-E/10/228**. Please use this reference number for all future correspondence.

Continued approval is conditional upon your compliance with the following requirements:

1. Only the approved Participant Information Sheet and Consent Form should be used. It must be signed by each subject prior to initiation of any protocol procedures. In addition, each subject should be given a copy of the signed consent form.
2. No deviation from, or changes of the protocol should be implemented without documented approval from the NHG DSRB, except where necessary to eliminate apparent immediate hazard(s) to the study subjects, or when the change(s) involves only logistical or administrative aspects of the trial (e.g. change of monitor or telephone number).
3. Any deviation from, or a change of, the protocol to eliminate an immediate hazard should be promptly reported to the NHG DSRB within seven calendar days.
4. Please submit the following to the NHG DSRB:
 - a. All unanticipated problems involving risk to subjects or others should be reported. In order to assist the DSRB, all reports should be accompanied by the NHG DSRB Unanticipated Problems Involving Risk to Subjects or Others Reporting Form. Please find all forms and guidelines on reporting on the internet at www.research.nhg.com.sg.
 - b. Report(s) on any new information that may adversely affect the safety of the subject or the conduct of the study.
 - c. NHG DSRB Project Status Report Form – this is to be submitted 4 to 6 weeks prior to expiry of the approval period. The study cannot continue beyond **16 June 2011** until approval is renewed by the NHG DSRB.
 - d. Study completion – this is to be submitted using the NHG DSRB Project Status Report Form within 4 to 6 weeks of study completion or termination.

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5. The NHG Research QA Program was launched in May 2006. The program aims to promote responsible conduct of research in a research culture with high ethical standards, and to identify potential systemic weaknesses and make recommendations for continual improvement. This research project may be randomly selected for completion of self assessment worksheet or for a study review by the QA team. For more information please visit www.research.nhg.com.sg.

Yours sincerely,



Prof Chng Hiok Hee
Chairperson
NHG Domain Specific Review Board E

Cc: Director of Research, NUH (via fax only)
c/o Office of Biomedical Research, NUH

Chief, Department of Medicine, NUH