



**JAWATANKUASA ETIKA & PENYELIDIKAN PERUBATAN**  
*(Medical Research & Ethics Committee)*  
**KEMENTERIAN KESIHATAN MALAYSIA**  
d/a Institut Pengurusan Kesihatan  
Jalan Rumah Sakit, Bangsar  
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Ruj. Kami : ( 12 )KKM/NIHSEC/ P15-343  
Tarikh : 27 July 2015

**Protocol Title :**

**NMRR-15-73-24008 (IIR)**

**Effectiveness of Group Cognitive Behavioral Therapy on Pain, Functional Disability and Psychological Outcomes among Knee Osteoarthritis Patients Seen at Malaysian Government Hospital**

**Principal Investigator/s :**

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**Dr Zubaidah Jamil Osman**  
**Jabatan Psikiatri**  
**Universiti Putra Malaysia**

**Documents received and reviewed with reference to the above study:**

1. Study Protocol Version 3 Dated 06-07-2015
2. Patient information sheet (English) & Informed Consent Form (English) Version 2 Dated 06-07-2015
3. Patient information sheet (BM) & Informed Consent Form (BM) Version 2 Dated 06-07-2015
4. Questionnaire version 1 dated 20-01-2015
5. Curriculum vitae of :
  - Foo Chai Nien
  - Prof Dr Lekhraj Rampal
  - Prof Dato' Dr Lye Munn Sann
  - Prof Dr Manohar Arumugam
  - Prof Sherina Bt Mohd Sidik
  - Dr Zubaidah Jamil Osman

Please note that the approval is valid until **26 July 2016**. The following are to be reported upon receiving ethical approval. Required forms can be obtained from the Medical Research Ethics Committee (MREC) website (<http://www.nih.gov.my/mrec>).

- v. **Continuing Review Form** has to be submitted to MREC at least 2 months before the expiry of the approval.
  - vi. **Study Final Report** upon study completion to the MREC.
  - vii. Ethical approval is required in the case of **amendments/ changes to the study documents/ study sites/ study team**.
  - viii. **Applicable for Clinical interventional Studies only:** Report occurrences of **all Serious Adverse Events (SAEs), Suspected Unexpected Serious Adverse Reaction (SUSARs) and Protocol Deviation/Violation** at all MREC approved sites to MREC. SAEs are to be reported within 15 calendar days from awareness of event by investigator. Initial report of SUSARs are to be reported as soon as possible but not later than 7 calendar days from awareness of event by investigator, followed by a complete report within 8 additional calendar days.
3. **262** number of subjects/ patients/ respondents are targeted to enroll this study in Malaysia.

Please take note that the reference number for this letter must be stated in all correspondence related to this study to facilitate the process.

Comments (if any):

Project Sites:

Hospital Serdang

Hospital Putrajaya

Decision by Medical Research & Ethics Committee:

Approved

Disapproved

Date of Approval : 27 July 2015



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**DATO' DR CHANG KIAN MENG**  
Chairperson  
Medical Research & Ethics Committee  
Ministry of Health Malaysia

