

**JAWATANKUASA ETIKA PENYELIDIKAN PERUBATAN**

**PUSAT PERUBATAN UNIVERSITI MALAYA**

ALAMAT: LEMBAH PANTAI, 59100 KUALA LUMPUR, MALAYSIA

TELEFON: 03-79493209 FAKSIMILI: 03-79492030

FAX NO: 6-03-79545682

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Chairman

Medical Ethics Committee

University Malaya Medical Centre

**ANNUAL STUDY REPORT** / **STUDY CLOSURE REPORT**

as of \_\_\_\_\_\_\_/\_\_\_\_\_\_\_/\_\_\_\_\_\_\_ (Date)

#### Applicable to studies that have commenced

*Form to be completed and signed by principal investigator only*

**TITLE OF STUDY:**

**MREC Ref. No :** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PROTOCOL NO :** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**SPONSOR :** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**DATE ACTUAL RANDOMIZATION/RECRUITMENT BEGAN** \_\_\_\_\_\_\_/\_\_\_\_\_\_\_/\_\_\_\_\_\_

*(Not screening)*

# STUDY STATUS:

## (Please tick one)

* Randomization/Recruitment Phase
* Recruitment completed, on-going follow-up

Expected completion date: \_\_\_\_\_\_/\_\_\_\_\_\_/\_\_\_\_\_\_

* Last Patient Last Visit reached
* All data clarified, study formally closed
* Early termination of study

Comments (if any):

No. of subjects recruited/randomized to date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### (Exclude screen failures, include drop-outs)

No. of active study subjects: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

No. of subject drop-out: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*(Exclude death)*

No. of deaths: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

No. of local Serious Adverse Event (SAE) ie. Death, admissions, life-threatening conditions etc in the previous 12 months: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Has every SAE been reported to MEC in accordance to GCP?

* Yes
* No
* N.A.

Comments (if any):

No. of protocol deviation/violations in the previous 12 months: \_\_\_\_\_\_\_\_\_\_

Has sponsor and MEC has been notified:

* Yes
* No
* N.A.

Comments (if any):

Additional Remarks (general):

Status of the study: Close ( )

 Ongoing ( )

Name of Principal Investigator: Date:

 **BK-QSU-025-E01**