YEAR:

Ref. No:

**

**JAWATANKUASA ETIKA UNIVERSITI UNTUK PENYELIDIKAN MELIBATKAN MANUSIA (JKEUPM)**

**UNIVERSITI PUTRA MALAYSIA, 43400 UPM SERDANG SELANGOR, MALAYSIA**

**SELANGOR, MALAYSIA**

**ETHICS COMMITTEE FOR RESEARCH INVOLVING HUMAN SUBJECTS (JKEUPM)**

**FORM 3.1 PROGRESS REPORT**

**Types of Study:  Clinical Trial**

 ** Non-Clinical Trial**

**Report no.: 1, 2, 3,  4,  5,  6,  7,  8**

All Clinical Trial progress reports must be submitted every six (6) months and non-clinical trials, annually. To be completed in typescript and submitted by the Principal Investigator. For questions with Yes/No options please indicate answer in bold type.

**1. Details of Principal Investigator**

|  |  |
| --- | --- |
| Name: |  |
| Address of institution: |  |
| Telephone: |  |
| E-mail: |  |

**2. Details of study**

|  |  |
| --- | --- |
| Full title of study: |  |
| Reference number: |  |
| Date of ethical approval: |  |
| Sponsor: |  |

#### 3. Commencement and termination dates

|  |  |
| --- | --- |
| Has the study started? | Yes / No |
| If yes, what was the actual start date? |  |
| If no, what is the expected start date? |  |

|  |  |
| --- | --- |
| Has the study finished? | Yes / No |
| If no, what is the expected completion date? |  |
| If you do not expect the study to be completed, give reason(s) |  |

**4. Site information**

|  |  |
| --- | --- |
| Name of study site: |  |
| Do you plan to increase the total number of sites proposed for the study?*Any increase in study site should be notified to the JKEUPM as a substantial amendment for ethical review.* | Yes / No |

**5. Recruitment of participants**

|  |  |
| --- | --- |
| Proposed in original application |  |
| Actual number recruited to date |  |
| Actual number completed to date |  |
| Number of subjects not completing trial to date: |
| (a) withdrawal of consent:  |  |
| (b) loss to follow-up:  |  |
| (c) death (where not the primary outcome):(d) other reasons:  |  |
| Total:  |  |
|  |  |
| Number of treatment failures to date (prior to reaching primary outcome) due to:  |
| (a) adverse events:  |  |
| (b) lack of efficacy:  |  |
| Total:  |  |

|  |  |
| --- | --- |
| Have there been any serious difficulties in recruiting participants? | Yes / No |
| If yes, give details: |  |
| Do you plan to increase the planned recruitment of participants into the study?*Any increase in planned recruitment should be notified to the JKEUPM as a substantial amendment for ethical review.* | Yes / No |

6. Safety reports

|  |  |
| --- | --- |
| Have there been any Suspected Unexpected Serious Adverse Reactions (SUSARs)/ safety issues\* in this trial? | *Yes / No* |
| Have these **SUSARs/** **safety issues\*** been notified to the JKEUPM?  | Yes / No |

\*Delete where applicable

**7. Risk/ benefit Ratio**

|  |  |
| --- | --- |
| Is the risk/ benefit ratio maintained? | *Yes / No* |
| If no, please elaborate. |  |

**8. Amendments**

|  |  |
| --- | --- |
| Have any substantial amendments been made to the trial during the year? | Yes / No |
| If yes, please give the date and amendment number for each substantial amendment made. |  |

**9. Other issues**

|  |  |
| --- | --- |
| Are there any other developments in the trial that you wish to report to the Committee?Are there any ethical issues on which further advice is required?*If yes to either, please attach separate statement with details.* | *Yes / No**Yes / No* |

 **I wish to apply for ethical approval extension (please tick)**

**10. Declaration**

**I confirm the above information is true.**

|  |  |
| --- | --- |
| Signature of Principal Investigator: |  |
| Name: |  |
| Date of submission: |  |