**Sunway Medical Centre Independent Research Ethics Committee (SREC)**

**RESEARCH APPROVAL APPLICATION CHECKLIST**

*(Please send 3 copies (1 original and 2 photocopies) of the completed application forms with supporting documents and this checklist to: SREC Secretariat, c/o SunMed Clinical Research Centre, Sunway Medical Centre, No. 5 Jalan Lagoon Selatan, Bandar Sunway 46150 Petaling Jaya, Selangor*

*Tel: 03-7491 1256 Fax: 7491 1255)*

|  |  |
| --- | --- |
| **Title of research project** |  |
| **Protocol number** |  |
| **Principal Investigator** |  |
| **Research site** |  |
| **Sponsor** |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***Documentation*** | ***Remark*** | | ***√ if attached and specify*** | | |
|  |  | | ***√*** | ***Version*** | ***Date*** |
| Proposal / Project Description / Protocol | *Compulsory*  *(Protocol is compulsory for clinical trials)* | |  |  |  |
| Investigator’s Brochure / Product Information Sheet | *Compulsory for clinical trials or research involving medical devices* | |  |  |  |
| Investigator’s Curriculum Vitae | *Compulsory (signed & date)* | |  |  |  |
| Co-investigator(s)’ or Supervisor(s)’ Curriculum Vitae | *Compulsory if co-investigator(s) or supervisor(s) exist (signed & date)* | |  |  |  |
| Investigator(s)’ GCP Certificate | *If any* | |  |  |  |
| Company Profile | *Compulsory for research in collaboration with private companies* | |  |  |  |
| Advertising Material(s) | *If any* | |  |  |  |
| Data Collection Instrument(s) | *Surveys / Questionnaires /Iinterview schedules (if any)* | |  |  |  |
| Subject Information Sheet (SIS)  \**please refer ‘Informed Consent Form & Written Subject Information Checklist’ (Checklist 2) as guidance* | *Compulsory for clinical trials (please attach available translations)* | *English* |  |  |  |
|  |  | *Bahasa Malaysia* |  |  |  |
|  |  | *Chinese* |  |  |  |
|  |  | *Other Languages* |  |  |  |
| Informed Consent Sheet (ICF)  \**please refer ‘Informed Consent Form & Written Subject Information Checklist’ (Checklist 2) as guidance* | *Compulsory for clinical trials (please attach available translations)* | *English* |  |  |  |
|  |  | *Bahasa Malaysia* |  |  |  |
|  |  | *Chinese* |  |  |  |
|  |  | *Other Languages* |  |  |  |
| Case Report Forms | *If any* | |  |  |  |
| Translation Certificate | *Compulsory for PIS and ICF attached in other languages (clinical trials)* | |  |  |  |
| Budget Allocation Sheet | *If any* | |  |  |  |
| Other Ethics Approval Letter | *If any* | |  |  |  |
| Institutional Approval / Letter of Support | *Compulsory for investigator-initiated study or student project* | |  |  |  |
| Letter of Indemnification | *Compulsory for industry-sponsored study* | |  |  |  |
| Insurance Statement | *Compulsory for industry-sponsored study* | |  |  |  |
| Others, specify: |  | |  |  |  |