**SunMed Research Request Form**

Please complete this form in order to request for research project to be done in Sunway Medical Centre (SunMed). Your request form and will be accessed internally and you shall be notified of SunMed CRC Research Board’s decision and/or recommendations. This form is only applicable for Investigator Initiated Research (IIR).

|  |
| --- |
| **General information** |
| Study Title  |  |
| Name of Principal Investigator (PI) |  |
| Department & Designation |  |
| Organisation / Institution / Company |  |
| Address |  |
| Email |  |
| Contact Number |  |
| Person in charge of the project (if any) i.e. Project manager, Research Assistant, Research officer |  |
| Name  |  |
| Contact number  |  |
| Project start date |  |
| Project end date  |  |

|  |
| --- |
| **Project Team Member** |
| **Name** | **Role** | **Designation** | **Institution & Department** | **Contact Number** | **Email** | **Sign and date** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

|  |
| --- |
| **Financial support for your research** |
| Funding plans and status | Are you requesting for funds for this study? Yes ( / ) No ( )  |
| Any other funds/grant applied? Yes ( / ) No ( ) Please specify:- Click here to enter text. |
| Estimated grant total (if known)Click here to enter text. |
| Name of sponsor(s)/Funder | Click here to enter text. |
| Amount of sponsorship/grant required | Click here to enter text. |
| Other sources of financial support Eg. Drug supply, equipment provision, commercial support and etc.  | Click here to enter text. |

|  |
| --- |
| **Study Information** |
| **Research Description and Rationale:** |
| **Objectives (General and Specific):** |
|  |
| **Study Design:** (Please provide a concise overview of the study design)* *Type of experimental design (e.g. RCT, cohort, cross-sectional, etc)*
* *Study population and recruitment period*
* *Sample size*
* *Inclusion & exclusion criteria*
* *Study process & duration (start and end date)*
 |
| **Statistical Plan:** (justification for sample size and primary hypothesis testing).  |
| **Data Storage and Rights:***\* Do note that any data collected from Sunway Medical Centre for research purposes will remain under the ownership of Sunway Healthcare Group and can be subjected to inspection, monitoring and audit.*  |
| **Budget Breakdown:** (if applying for funds) |
| **Publication Plan:** |

|  |
| --- |
| **Authorship**  |
| *Please have all authors sign and date. Please list all the manuscript authors and their contributions. If an additional author(s) and signature fields are needed, please insert row as needed.* |
|  | *Role in the project* | *Contribution* | *Name* | *Sign* | *Date* |
| Corresponding Author |  |  |  |  |  |
| First Author |  |  |  |  |  |
| e.g. Second Author |  |  |  |  |  |
| e.g. Third Author |  |  |  |  |  |

|  |
| --- |
| **Delegation Log****All roles should be delegated as appropriate or the role will remain the responsibility of the Chief Investigator (CI)/Principal Investigator (PI)** |
| **Name** | **Title** | **Role** | **Delegated study Task(s)** | **Initials** | **Signature** | **Date** | **Duration (dd/mmm/yyyy)** | **CI/PI** |
| **Start date** | **End date** | **Signature** | **Date** |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

**FOR COMPLETION AT TRIAL CLOSURE:** The individuals listed on this log are suitably qualified and have received appropriate training related to

their respective tasks for this protocol. I assert that these duties were performed under my direct supervision.

CI/PI Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date (dd-mmm-yyyy):

|  |
| --- |
| **Support required** |
| Please specify: - | *NIL* |

|  |
| --- |
| **Mandatory**  |
| **Anti-Bribery and Corruption Policy** SUNWAY BERHAD Group has adopted a **ZERO TOLERANCE** policy against all forms of bribery and corruption. Sunway Berhad Group (hereinafter referred to as “SUNWAY” or “The Company”) is committed to conducting its business in accordance with all applicable laws, rules and regulations and the highest ethical standards. It reiterates SUNWAY’s commitment to full compliance by its Employees and Associates with the Malaysian Anti-Corruption Commission (MACC) Act 2009 and the MACC (Amendment) Act 2018 and any other local anti-bribery or anti-corruption laws that may be applicable. All investigators and research team are required to comply with the Sunway Berhad Group anti-bribery and corruption policy. **MSQH, JCI and ACHS Requirements** Sunway Medical Centre is an Australian Council on Healthcare Standards (ACHS) and Malaysian Society for Quality in Health (MSQH) accredited private hospital. Therefore, all investigators and research team must also comply with the appropriate Malaysian Accreditation Organisation for Healthcare Facilities and Services (MSQH), Joint Commission International (JCI) standards (JCI) and Australian Council on Healthcare (ACHS) standards for the part of service which functions within the clinical research. This applies to all research projects that carried out in Sunway Healthcare Group Hospitals. **Training and Delegation** The investigator is responsible to ensure that all the research team members are educated, trained and qualified to carry out his/her responsibilities. The investigator should ensure that all persons assisting with the research are adequately informed about the protocol, the investigational product(s) (if applicable), and their research-related duties and functions (GCP 4.2). All training conducted must be documented in the training log. The investigator should also maintain a list of appropriately qualified persons to whom the investigator has delegated research-related duties. Please take notes that you may be asked to provide the training evidence and delegation log during a research audit or inspection.**Guide:**The training plan for Investigator Initiated Research (IIR) should include but not limited to the following:* Site SOPs (if applicable)
* Research project specific training
* Protocol: include subject visit schedule, data collection procedures, and procedures which differ from routine standard of care and accessing eligibility and exclusion criteria.
* Consent procedure: verbal consent/written consent.
* Research documentation: What is required, from whom, and by when
* Data Entry into Case Report Form
* Source documents
* Database training (if applicable)
* Filing and archiving
* Laboratory specimen processing (if applicable)
* Specific skills or any additional training may be necessary depending on the approved research protocol.
* Others as deemed necessary by the PI.

The training plan for **clinical trial involving investigational products** should include (but not limited to) the following:* Investigator Meeting (IM)
* Site Initiation Visit (SIV)
* GCP/GCP refresher training (applicable for clinical trial involving investigational products or multicentre trials)
* Site SOPs (applicable for clinical trial involving investigational products or multicentre trials)
* Trial-specific Training
* Protocol: include trial schedule, trial procedures, routine procedures, and procedures which differ from routine standard of care, eligibility criteria.
* Consent procedure: including trial specific consent procedure (if applicable).
* Pharmacovigilance reporting requirement: including Sponsor’s requirements and trial specific requirements. e.g.: Adverse Event (AE) and Serious Adverse Event (SAE) reporting and etc.
* Investigational Product (IP) management: including safety information from available documentation, treatment schedule according to the protocol.
* Trial documentation: what is required, from whom, and by when e.g.: Data Entry into Case Report Form.
* Laboratory specimen processing.
* Specific skills or any additional training may be necessary depending on the approved trial protocol.

Do note that any data collected from Sunway Medical Centre for research purposes will remain under the ownership of Sunway Healthcare Group and can be subjected to inspection, monitoring and audit. **Mandatory before research project could be approved by the institution.** * Read, understand and comply the Sunway Berhad Group anti-bribery and corruption policy.
* **Complete the Investigator and Research Team Anti Bribery and Corruption Declaration Form** (See appendix A). Please attach the completed Investigator and Research Team Anti Bribery and Corruption Declaration Form with the completed SMRR form to CRC.
* **A complete study proposal must be submitted for scientific review.**
 |

|  |
| --- |
| Confirmation  |
| I confirm that the information given in this form is true, complete and accurate. |
| I will comply with the Sunway Berhad Group anti-bribery and corruption policy and the appropriate Malaysian Accreditation Organisation for Healthcare Facilities and Services (MSQH), Joint Commission International (JCI) standards (JCI) and Australian Council on Healthcare (ACHS) standards.  |
| I will submit my bi-annually progress reports to Clinical Research Centre (CRC) by 1st May and 1st November.  |
| I will notify CRC for any changes/amendments made in my research project. Changes are not limited to delegation log/research team member, amendments in research proposal, or/and any written documents provided to the subjects.  |
|  I am aware of SunMed research related policies and procedures and I shall adhere to the policies and procedures (Refer to page 10). |
| Signature: Name: Date :  |

Appendix A

**Anti-Bribery and Corruption Declaration Form For Investigator and Research Team**

I have read and understood the contents, requirements and responsibilities required of me in relation to the following policies below:

☐ Anti-Bribery & Corruption Policy

☐ Gifts, Entertainment & Hospitality Policy

☐ Donations, Sponsorships & Corporate Responsibilities Policy.

2. I agree to adopt a zero tolerance approach to bribery and corruption and comply with the requirements and provisions set out in the said Policies and Procedures.

 3. I agree to comply with the Malaysian Anti-Corruption Commission (MACC) Act 2009 and the MACC (Amendment) Act 2018 or any other applicable laws and regulations relating to anti-bribery and corruption which I am subject to.

4. I understood the Basic Rules on Gifts, Entertainment & Hospitality stipulated in the Anti Bribery Corruption Policy and undertake to apply them in my day to day research activities/actions, decisions and interactions with internal and external parties.

5. I understand that if there is any violation of the said Policy and Procedures, it may result in legal action being taken against myself, including dismissal or research project termination and other legal actions.

Signature:

Name:

Date:

CRC OFFICE USED

Received by:

Date:

List of Policies and Procedures in CRC

|  |  |  |
| --- | --- | --- |
| **Policy number**  | **Policy name**  | **Applicability**  |
| **SMC-GL-CORP-CRC-001** | **Prepare for an Audit or Inspection**  | **IIR** |
| **SMC-GL-CORP-CRC-002** | **External Grant Application for Investigator Initiated Research (IIR)**  | **IIR** |
| **SMC-GL-CORP-CRC-003** | **Grand Management for Investigator Initiated Research (IIR)** |  **IIR**  |
| **SMC-SOP-CORP-CRC-007** | **Request for Research collaboration with SunMed** | **IIR** |
| **SMC-SOP-CORP-CRC-008** | **SunMed Funding Application** | **IISR**  |
| **SMC-SOP-CORP-CRC-009** | **Document Control for research Related Documents** | **ISR, IISR** |
| **SMC-SOP-CORP-CRC-010** | **Protocol Development** | **IISR (if applicable)** |
| **SMC-SOP-CORP-CRC-013** | **Informed Consent Process** | **ISR**  |
| **SMC-SOP-CORP-CRC-016** | **Re-consent process** | **IIR** |
| **SMC-SOP-CORP-CRC-017** | **Taking Informed Assent Process** | **IIR** |
| **SMC-SOP-CORP-CRC-019** | **Research Team Training** | **IIR, IISR, ISR** |
| **SMC-SOP-CORP-CRC-020** | **Handling of Research Noncompliance** | **IIR, ISR** |
| **SMC-SOP-CORP-CRC-021** | **Assisting in Site Initiation Visit for ISR** | **ISR** |
| **SMC-SOP-CORP-CRC-022** | **Assisting in (COV) for Industry Sponsored Research (ISR)** | **ISR** |
| **SMC-SOP-CORP-CRC-023** | **Assisting in Archiving in (ISR)** | **ISR** |
| **SMC-SOP-CORP-CRC-027** | **Safety Surveillance Management**  | **ISR, IISR** |
| **SMC-SOP-CORP-CRC-028** | **Research Sample Management** | **ISR** |
| **SMC-SOP-CORP-CRC-029** | **Submitting Study Progress Report & End of Research Report** | **ISR, IISR** |
| **SMC-SOP-CORP-CRC-030**  | **Laboratory Specimen Handling & Shipment in (ISR)** | **ISR** |
| **SMC-SOP-CORP-CRC-031** | **Investigational Product (IP) Management** | **ISR, IISR** |
| **SMC-SOP-CORP-CRC-032** | **Investigational Product (IP) Dispensing**  | **ISR, IISR** |
| **SMC-SOP-CORP-CRC-033** | **Study Closeout for Investigator Initiated Research (IIR)** | **IISR (If applicable)** |
| **SMC-SOP-CORP-CRC-034** | **Site Initiation for Investigator Initiated Research (IIR)** | **IIR** |
| **SMC-SOP-CORP-CRC-035** | **Maintaining Study Documentation & Record Keeping in Industry Sponsored** | **ISR, IISR** |
| **SMC-SOP-CORP-CRC-036** | **Monitoring of Investigator Initiated Research (IIR)** | **IIR** |
| **SMC-SOP-CORP-CRC-037** | **Handling Feasibility Studies** | **ISR** |
| **SMC-SOP-CORP-CRC-038** | **Research Misconduct** | **ISR, IISR** |
| **SMC-SOP-CORP-CRC-039** | **Pre publication Submission Review** | **IISR**  |
| **SMC-SOS-CORP-CRC-001** | **Clinical Research Department** | **IIR**  |

Access to shared point to read to the policies and procedures.

If your study is not a clinical trial, kindly refer to IIR related policies and procedures.

For Clinical Trial please refer to ISR or IISR related policies and procedures.

Contact CRC if you required further assistance.