**Sunway Clinical Research Centre (SCRC)**

1. Please complete **Section A** to request authorization for conducting a research project at Sunway Healthcare Group facilities. Your request will be reviewed by Sunway Clinical Research Centre and Sunway Medical Research Board (SRB). This form is intended solely for Investigator Initiated Research (IIR).
2. Please submit a **complete study proposal/protocol** along with this SMRR form for scientific review.
3. Ensure you carefully review, understand, and comply with the Policies and Requirements outlined in **Section B**, as well as acknowledge the following essential documents for institutional approval of your research project:

1. Anti-Bribery and Corruption Declaration Form for Investigator and Research Team (see **Section C**).
2. Conflict of Interest Declaration Form for Investigator and Research Team (see **Section D**).
3. Data Privacy and Confidentiality Form (see **Section E**).
4. Please read and adhere to the Sunway Medical research-related policies and procedures when conducting research at the Sunway Healthcare facility. The documents can be accessed at the Sunway Medical Centre SharePoint (<https://sunwaysharedservices.sharepoint.com/sites/sunmed>).
5. If you have any enquiries, please contact Sunway Clinical Research Centre (SCRC) at sunway\_crc@sunway.com.my or 03-8601 1079.

**SECTION A: RESEARCH INFORMATION**

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| 1. **General Information**
 |
| Study Title  | Click or tap here to enter text. |
| Name of Principal Investigator (PI) | Click or tap here to enter text. |
| Department & Designation | Click or tap here to enter text. |
| Organisation / Institution / Company | Click or tap here to enter text. |
| Address | Click or tap here to enter text. |
| Email | Click or tap here to enter text. |
| Contact Number | Click or tap here to enter text. |
| Name of Person in Charge (PIC) of the project (if different from PI)i.e. Project Manager, Research Assistant, Research Scientist | Click or tap here to enter text. |
| PIC Contact Number  | Click or tap here to enter text. |
| Project Start Date | Click or tap here to enter text. |
| Project End Date (Expected) | Click or tap here to enter text. |

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| 1. **Project Team Member**
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| **Name** | **Role** | **Designation** | **Institution & Department** | **Contact Number** | **Email** | **Sign and date** |
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| 1. **Financial Support for Your Research**
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| Funding Plans and Status | Will you be applying for Sunway Medical Research Funding for this study?Yes ([ ] ) No ([ ] )  |
| Have you applied for any other funds or grants?Yes ([ ] ) No ([ ] ) Please specify: - Click here to enter text. |
| Estimated total amount of fund/grant (if known)? Click here to enter text. |
| Name of Sponsor(s) / Funder(s) | Click here to enter text. |
| Amount of Sponsorship / Grant Required | Click here to enter text. |
| Other Sources of Financial Support (e.g., drug supply, equipment provision, commercial support, etc.) | Click here to enter text. |

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| 1. **Delegation Log**

All roles should be delegated as appropriate or the role will remain the responsibility of the Principal Investigator (PI) |
| **Name** | **Role** | **Delegated Study Task(s)** | **Initials** | **Signature** | **Date** | **Duration****(dd-mmm-yyyy)** | **PI** |
| **Start Date** | **End Date** | **Signature** | **Date** |
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**For Completion at Study Closure:** The individuals listed on this log are suitably qualified and have received appropriate training related to their respective tasks for this protocol. I affirm that these duties were performed under my direct supervision.

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

**SECTION B: POLICIES AND REQUIREMENTS**

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| **POLICIES AND REQUIREMENTS** |
| 1. **Anti-Bribery and Corruption Policy Statement**

Sunway Healthcare Group has adopted a **ZERO TOLERANCE** policy against all forms of bribery and corruption. Sunway Healthcare 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 Healthcare Group anti-bribery and corruption policy. 1. **Conflict of Interest (COI) Policy Statement**

Conflict of Interest (COI) (real, potential or perceived) arises when and individual in a position of trust has competing professional or personal interest. Such competing interests may influence his/her professional judgement, objectivity and independence and can potentially influence the outcome of a decision, for personal benefit. A conflict of interest may exist even if no unethical or improper acts result from the conflict.Investigator(s) should identify and manage COI to maintain the public confidence and trust to maintain the independence and integrity of the ethics review. If a COI cannot be avoided, procedures should be put into place to mitigate the conflict. Examples of COI might include the following, although it is not an exhaustive list:* Having received fees for consulting.
* Having received funds reimbursing the investigator for attending a related symposium, or talk.
* Holding stocks or shares in a company which might be affected by the publication of the paper resulted from the research.
* If there are other interests which the reasonable that investigator might feel will affect the research, the investigator may also wish to declare them.

All new research project applications required the Principal Investigator to make a Conflict of Interest (COI) declaration for the research project. The declaration should be made upon application or before the commencement of the research project. Principal Investigator is additionally required to provide information on the research budget, as applicable, when submitting the research. Such disclosure shall be in writing and sufficiently detailed to allow accurate and objective evaluation of conflict.In the event that there is a change in status in areas where the possibility of COI may arise, the research member must make a declaration by completing and submitting the COIDR form (Part D) within 30 days of the change to the Sunway Clinical Research Centre (SCRC) and SREC. If the investigator is not clear whether the situation is a COI, the investigator may contact the SCRC for clarification.1. **Data Privacy and Confidentiality Policy Statement**

Sunway Healthcare Group is committed to ensuring proper and adequate protection of Personal Data within its control, in compliance with the Act and the laws mentioned below:1. Personal Data Protection Act 2010
2. Personal Data Protection Standard 2015
3. Private Healthcare Facilities Act 1998, the Private Healthcare Facilities and Services (Private Hospitals and other Private Healthcare Facilities) Regulation 2006 (the “2006 Healthcare Regulation”)

Principal Investigator is responsible for the integrity of the stored data. The data protections and confidentiality protocols should be in place before the research starts, and includes aspects like thefts, loss or tampering of the data by limiting the access to the research data. Access to information about individual participants should be restricted to the investigators/researchers and any research assistant(s) on a need-to-know-basis.Principal Investigator and/or research team member(s) should not process Personal Data of the research subject without obtaining his/her consent and the statement of obtaining research subject’s personal data should me mentioned in the research Informed Consent Form (ICF) (if any).Example of Personal Data, Sensitive Personal Data and documents which may contain such data are summarised in table below:

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| **Personal Data** | **Sensitive Data** | **Documents Which May Contain Such Data** |
| Name | Physical or mental health or condition | Inform Consent Form (ICF) |
| NRIC number / Passport number | Political opinion | Patient Registration Form |
| Address | Religious belief or other belief of a similar nature | Enquiry form |
| Contact details | Commission or alleged commission of any offence |  |
| Photographs |  |
| CCTV recordings |
| Bank account details |
| Income |
| Occupation |
| Academic records |

Principal Investigator shall notify SCRC and SREC immediately in writing (but in no event later than three (3) days from the date) of any of the following events:1. loss or misuse (by any means) of personal data of research participants;
2. inadvertent, unauthorized, and/or unlawful processing, collection, storage, disclosure, access, alteration, corruption, transfer, destruction, or use of personal data of research participants or;
3. any other act or omission that compromises the security, confidentiality, or integrity of personal data of research participants to enable the SCRC and/or SREC to consider what action is required in order to resolve the issue in accordance with applicable Data Protection Laws. If requested by SCRC and/or SREC in order to enable Sponsor to comply with applicable Data Protection Laws, Institution and Investigator will, and will cause its research team member(s) to assist and cooperate with SCRC and/or SREC to address any data protection/privacy issue relating to the research.

Do note that any data collected from Sunway Healthcare Group for research purposes will remain under the ownership of Sunway Healthcare Group and can be subjected to inspection, monitoring and audit. 1. **Compliance to the Accreditation Bodies Requirements**

Sunway Healthcare Group Hospitals are committed adhering to the standards and regulation from the accreditation bodies such as Australian Council on Healthcare Standards (ACHS), Joint Commission International (JCI) and Malaysian Society for Quality in Health (MSQH). Therefore, all research conducted at Sunway Healthcare Group facilities must adhere to the standards and requirements of the accredited bodies received by the respective hospital. Investigators and research team must also comply with the appropriate standards and requirements 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.  |

**Important: It is compulsory to read, understand and comply with the policy statements mentioned in Section B (i-iii).**

**SECTION C: ANTI-BRIBERY AND CORRUPTION DECLARATION FORM FOR INVESTIGATOR AND RESEARCH TEAM**

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| **DECLARATION ANTI-BRIBERY AND CORRUPTION** |
| **Declaration** | **Please tick (/) as applicable** |
|  | **Yes** | **Not Applicable** |
| 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
 |[ ] [ ]
| 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. |[ ] [ ]
| 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. |[ ] [ ]
| I understand 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. |[ ] [ ]
| 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 : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**SECTION D: CONFLICT OF INTEREST DECLARATION FORM FOR INVESTIGATOR AND RESEARCH TEAM**

It is the policy of Sunway Clinical Research Centre (SCRC) to ensure all the investigators declare their conflict of interest (financial or otherwise) that may have a direct bearing on the subject matter of the research. Please refer to Conflict of Interest (COI) Policy Statement in Part B (ii).

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| **Financial Interest**  |
| 1. Financial interests include opportunities where an individual uses his/her professional judgment for personal financial gain or to benefit a company in which the individual has a financial interest such as a patent, trademark, copyright, licensing agreement, ownership interest, or stock options. Or, a research team member could be influenced by substantial payments that may be upcoming. This might include, for example, a grant to fund similar research or one that competes with the investigator’s respective study.
2. "Significant financial interest" refers to anything of monetary value, including a salary, consulting fee, honorarium or other payment for service; equity interests, including stocks, stock options or other ownership interests; and intellectual property rights, including patent rights owned by the investigator or on which a clinical investigator is a named inventor (whether licensed or not), copyrights and royalties.
 |
| 1. This Policy on Investigators’ Conflicts of Interest, however, excludes from consideration the following items:
	1. Salary, or other remuneration (not including royalties) from Sunway Group.
	2. Income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities.
	3. (c) Income from service on advisory committees or review panels sponsored by public or non-profit entities.
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| **Non-Financial Interest** |
| Personal | When an individual’s other interests may impact the research study’s results, staff, or participants. |
| Professional | When an individual has the opportunity for professional growth based on his/her involvement in the research study |
| Institutional | When the benefits and/or financial interests of an institution may affect or appear to affect the research or other activities of the institution. |
| Perceived | When the appearance of a conflict is known to others and may bring about questions regarding the appropriateness of that individual’s involvement in the study. |
| Accepting gifts such as meals, drug samples, etc. from a company which could be interpreted as willingness to impact research data. |
| Receiving consulting fees from the research study company while performing |
| Owning stock in a company while performing clinical research sponsored by the company receiving milestone incentives such as payments, stock options, gifts, etc. |
| **DECLARATION CONFLICT OF INTEREST** |
| **Declaration** | **Please tick (/) as applicable** |
|  | **Yes** | **Not Applicable** |
| I have ***nothing to declare*** with respect to any current or potential interest or conflict in relation to this research (or any potential providers who may be subcontracted to deliver this work, their advisers or other related parties). By conflict of interest, I mean, anything which could be reasonably perceived to affect the impartiality of this research, or to indicate a professional or personal interest in the outcomes from this research. |[ ] [ ]
| I ***wish to declare*** the following with respect to personal or professional interests related to relevant organisations**\***:* <Insert your input here>

*Where a potential conflict of interest has been declared for an individual or organisation within a consortium, please clearly outline the role which this individual or organisation will play in the proposed project and how any conflict of interest has or will be mitigated.***\*** These may include (but are not restricted to);* A professional or personal interest in the outcome of this research.
* For evaluation projects, a close working, governance, or commercial involvement in the project under evaluation.
* Current or past employment with relevant organisations.
* Payment (cash or other) received or likely to be received from relevant organisations for goods or services provided (Including consulting or advisory fees).
* Gifts or entertainment received from relevant organisations
* Shareholdings (excluding those within unit trusts, pension funds etc.) in relevant organisations
* Close personal relationship or friendships with individuals employed by or otherwise closely associated with relevant organisations
 |[ ] [ ]

***Note:* A Declaration of Interest Will Not Necessarily Mean the Individual or Organisation Cannot Work on The Research Project; But It Is Vital That Any Interest or Conflict Is Declared So It Can Be Considered Openly.**

Signature : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

**SECTION E: DATA PRIVACY AND CONFIDENTIALITY FORM**

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| **DECLARATION OF DATA PRIVACY AND CONFIDENTIALITY**  |
| **Declaration** | **Please tick (/) as applicable** |
|  | **Yes** | **Not Applicable** |
| I have read and understood the contents, requirements and responsibilities required of me in relation to data privacy and confidentiality as mentioned in section B (iii).  |[ ] [ ]
| I agree to be responsible for the integrity of the stored data. I will ensure that data protections and confidentiality protocols should be in place before the research starts, and includes aspects like thefts, loss or tampering of the data by limiting the access to the research data.  |[ ] [ ]
| I agree to take full responsibility to ensure the access to information about individual participants will be restricted to the investigators/researchers and any research assistant(s) on a need-to-know-basis. |[ ] [ ]
| I shall notify SCRC and SREC immediately in writing (but in no event later than three (3) days from the date) of any of the following events:1. loss or misuse (by any means) of personal data of research participants;
2. inadvertent, unauthorized, and/or unlawful processing, collection, storage, disclosure, access, alteration, corruption, transfer, destruction, or use of personal data of research participants or;
3. any other act or omission that compromises the security, confidentiality, or integrity of personal data of research participants to enable the SCRC and/or SREC to consider what action is required in order to resolve the issue in accordance with applicable Data Protection Laws. If requested by SCRC and/or SREC in order to enable Sponsor to comply with applicable Data Protection Laws, Institution and Investigator will, and will cause its research team member(s) to assist and cooperate with SCRC and/or SREC to address any data protection/privacy issue relating to the research.
 |[ ] [ ]
| I understand that any data collected from Sunway Healthcare Group for research purposes will remain under the ownership of Sunway Healthcare Group and can be subjected to inspection, monitoring and audit.  |[ ] [ ]
| 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 : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Acknowledgement**

Please tick the box to confirm that you have read and understood the statements below:

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| [ ]  | I understand that I must complete Section A and submit a full proposal/protocol along with the SMRR form as part of the submission process. |
| [ ]  | I confirm that I have read and fully understand Section B and agree to comply with all requirements and guidelines outlined therein. |
| [ ]  | I confirm that the information provided in Sections C, D, and E is true, complete, and accurate to the best of my knowledge. |
| [ ]  | I acknowledge that I am aware of Sunway Medical’s research-related policies and procedures available on SharePoint and agree to adhere to them. |

Signature : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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