**PROTOCOL TEMPLATE FOR INVESTIGATOR-INITIATIED RESEARCH (IIR) AT SUNWAY HEALTHCARE FACILITY**

**NOTE: This page provides instructions for using this template and should not be included in the final protocol.**

1. This template is suitable for most study designs and includes the key elements that the Sunway Medical Research Ethics Committee (SREC) considers during protocol review.
2. Please read the *<hints/instructions>* carefully and only insert relevant information.
3. Examples of the required information are provided where applicable, such as <Example: These are suggested details that can be included>.
4. If a section is not applicable, **do not delete it**; instead, indicate **NOT APPLICABLE**.
5. Be sure to delete the all *<hints/instructions>* and <Examples>before submitting your finalized proposal/protocol.

**Study Protocol**

**<Protocol Title>**

**Protocol short name, version number and date:**

<Example: CRAN-24, Version 1.0, 1 January 2024>

**PRINCIPAL INVESTIGATOR:** <Example: Dr ABC>

**DEPARTMENT** <Example: Oncology>

**Address** <Example: Sunway Medical Centre>

**Telephone** <Example: 012-34567891>

**Fax Number** <Example: NOT APPLICABLE>

**E-mail** <Example: jc@yahoo.com>

**CO-INVESTIGATOR/S:** <Example: Dr ABC>

**DEPARTMENT** <Example: Oncology>

**Address** <Example: Sunway Medical Centre>

**Telephone** <Example: 012-34567891>

**Fax Number** <Example: NOT APPLICABLE>

**E-mail** <Example: jc@yahoo.com>

**RESEARCH COORDINATOR/**

**ASSISTANT:** <Example: Dr ABC>

**DEPARTMENT** <Example: Oncology>

**Address** <Example: Sunway Medical Centre>

**Telephone** <Example: 012-34567891>

**Fax Number** <Example: NOT APPLICABLE>

**E-mail** <Example: jc@yahoo.com>

**<Duplicate these sections, if there are additional project team members. >**

**DURATION OF PROJECT** <Example: 12 months>

**Start date** <Example: 01 Dec 2023>

**End date** <Example: 31 Dec 2024>

**Name and Address of Sponsor**  <If any. Example: Sunway Medical, MOSTI, etc >

**Participating/Collaborating site(s) address and contact number:**

<Example: Sunway Medical Centre, Hospital XYZ>

**PROPOSED BUDGET** <If any, applicable for applicant applying to Sunway Medical Research Fund. Otherwise, put NOT APPLICABLE>

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**LIST OF ABBREVIATIONS**

<List abbreviations/acronyms used throughout the protocol>

|  |  |
| --- | --- |
| <Abbreviation> | <Full Text> |
| <Abbreviation> | <Full Text> |
| Example: |  |
| CRF | Case Report Form |
| FUP | Follow-up |

**RESEARCH SYNOPSIS**

|  |  |
| --- | --- |
| Study title | <State the full title. Where applicable, suggest title should contain the following information – P (study population), I (intervention), C (comparator), O (outcome), S (study design)><Example: A randomized double blinded placebo controlled study on the efficacy of drug A in reducing hypertension in patients with condition C> |
| Primary Study Objective  | <Insert primary objective as stated in OBJECTIVE section below><Example: To determine the efficacy of drug A compared with placebo, in patients with condition C> |
| Specific Aims | <Insert specific aims as stated in OBJECTIVE section below><Examples: 1. To determine the difference in reduction of blood pressure
2. To determine the difference in need for hospitalization>
 |
| Study Population/Patient group | <Include a brief description of the population such as health status, gender, age, etc.><Example: All adult patients undergoing elective surgery in Hospitals MNB and TGH during the period 1 Oct 2015 – 1 April 2016> |
| Study Design | <State overview of the study design><Example: A randomized double blind placebo controlled study. Selected subjects will be randomized into treatment and placebo groups in a ratio of 1:1. Treatment and placebo will be taken at 4 mg b.i.d for 3 weeks><Example: A retrospective cross-sectional study. Medical records for the period Jan-Jun 2015 of selected subjects will be reviewed and study data extracted> |
| Sample Size | <State total number of participants for the study from all sites><Example: 40 subjects> |
| Study Endpoints/Outcomes | <Insert study endpoints or outcomes><Example: (a) change in blood pressure 14 days after initiation of treatment; (b) adverse events during study> |
| Study Duration | <State period in which study will be conducted> <Example: 1 October 2020 - 31 December 2021> |
| Placing a tick (/) in the appropriate types of information that will be obtained from the hospital’s clinical database? (If applicable) | [ ]  | Demographics |
| [ ]  | Medical history |
| [ ]  | Laboratory data  |
| [ ]  | Imaging data |
| [ ]  | Treatment information |
| [ ]  | Others: <If any, please specify> |
| Tissue needed | [ ]  Yes[ ]  NoIf yes, please specify tissue type:< If any, please specify >Amount of sample required: < If any, please specify > |

# 1. STUDY BACKGROUND

<This section is based on your research question >

<Start with what you know about the area, existing knowledge based on what has been published, describe the disease/condition under consideration, including incidence or magnitude of problem. State how others have addressed the issue of concern that we want to study and summarize their findings. Provide a summary of previous pre-clinical studies, relevant clinical studies, any epidemiological data, etc.>

<Then state what we want to find out or why the concerned areas need to be addressed. Justify your approach to the issue and rationale for specifications of the study interventions. For experimental study, state known information on the investigational product (study drug) / medical device or experimental procedure>

<In the last paragraph state what you want to research upon, the main purpose of the study>

## 2. PRIMARY OBJECTIVES AND SPECIFIC AIMS

<State the main purpose and specific aims of this research study>

# 3. SIGNIFICANCE AND EXPECTED CONTRIBUTION OF THE STUDY

< State significance and expected contribution or impact of conducting this study>

# 4. METHODOLOGY

**4.1 Study Type and Design**

# <Include the description of study type such as epidemiology study, diagnostic study, prognostic study or experimental /interventional study>

# <State the study design, for example, observational studies such as cross-sectional which include survey, cohort, case control or experimental study such as randomized control trial.

# <State whether the data collection is prospective and/or retrospective. Type of study and design should be decided on the basis of proposed objectives, study endpoints, and availability of the resources>

<In this section, the definition for the endpoints/variables used should be specified in detail, along with the ways and schedule to measure them>

<For interventional or experimental study on drug or medical device:

* Describe and provide rationale for the type of intervention, route of administration, dosage, treatment period, etc.
* State how compliance of subject is monitored.
* For study on medical device, state specification of the device. State any permitted and not permitted, and rescue medications / treatments during the study.
* Include information and rationale on use of placebo, washout, withholding treatment, randomization, blinding, etc.>

<State the number of study groups and ratio of subjects in control and treatment group>

<For qualitative data collection like surveys and interviews, describe the instrument such as questionnaires to be used and its rationale>

# 4.2 Study Population

## <State where subjects will be recruited from>

## <Example: All adult patients undergoing elective surgery in Hospitals MNB and TGH during the period 1 Oct 2015 – 1 April 2016>

## 4.2.1 Inclusion Criteria

<State the criteria for including individuals in the study>

<Example: Each potential participant must satisfy all the following criteria to be enrolled in the study:

* Be ≥18 years of age at the time of informed consent
* Have adequate organ and bone marrow function, without history of red blood cell transfusion or platelet transfusion within 7 days prior to the date of the laboratory test>

## 4.2.2 Exclusion Criteria

<State the criteria for excluding individuals from the study>

## 4.2.3 Withdrawal Criteria

<State any criteria for withdrawal of subjects. Include follow-up procedures and whether withdrawn subjects are replaced. When a participant withdraws before study completion, the reason for withdrawal is to be documented in the Case Report Form and in the source document. If the reason for withdrawal from the study is withdrawal of consent, then no additional assessments are allowed>

<Example: Subjects can choose to withdraw at any time. Subjects may be withdrawn if the investigator deems that it is detrimental or risky for the subject to continue. All withdrawn subjects should attend the final study visit. Withdrawn subjects will not be replaced>

## 4.2.4 Sample Size

<Insert calculations for the sample size. Clearly show and justify the parameters used. List the published literature that is referred to for the sample size in the event that sample size cannot be calculated>

<Example: Based on a power of 80% (β=0.2), alpha of 0.05, an expected outcome difference of 16% and standard deviation of 8% between the 2 study interventions, the calculated sample size for each group is 18 patients. Allowing for 10% dropout, a final sample size of 20 per group will be used>

**4.3 Biospecimen Handling**

<If applicable only>

<If not applicable, state that there is no biospecimen handling in this study>

<State types and quantities of biospecimens collected and the frequency. State how the specimens are stored and processed. State whether specimens are collected for genetic studies. State whether specimens are collected and used for future studies; include justification>

# 4.4 Study Duration and Timeline

<State projected start and end dates of study. Briefly state the duration of stages of your study>

Example:

* Stage 1: review of medical records – 4-6 months
* Stage 2: data collection and data analysis - 8-12 months
* Stage 3: presentation and publication - 6-12 months

<State duration of each subject’s participation>

<Example: The participation duration for each subject is 6 months>

**4.5 Study Visits and Procedures**

<This section should list study visits, observations and measures that will occur at each visit (if applicable). These can be detailed in table format as Gantt chart to be included in Appendix 2>

# 4.6 Statistical Analysis

<State the statistical tests to be used. Consult a biostatistician before you finalize your protocol. Include plan of accounting for missing, unused and spurious data>

<Example: The data analysis will be done using SPSS version 29.0. Descriptive data will be expressed as mean ± standard deviation (SD) unless otherwise stated. One-way ANOVA will be used for analysis of normally distributed variables. Kruskal-Wallis ANOVA will be used for non-normally distributed data. Categorical data will be analyzed using Chi-square or Fisher’s exact test. A value of p< 0.05 is considered statistical significant. The data collected will be analyzed using an intention-to-treat basis>

**4.7** **Termination of Study**

# <Insert any criteria for termination of study and subsequent follow-up>

# <Example: The investigator may decide to terminate the study at any time. Subjects will be informed if the study is terminated and follow-up visits will be arranged if needed>

**5. RISK AND BENEFIT**

**5.1 Risk and Benefit to Study Participants**

<Identify any potential risk involved while participating in the study>

<Example: It is known that there are no serious side effects caused by the investigational product. The study procedures are all routine procedures for the disease/condition studied. There is thus minimal risk for subjects>

<Include any benefits to the participant or to the overall research field>

<Example: This study does not present any direct benefit to the participants. However, the study does provide a better understanding of the disease/condition studied>

**5.2 Risk Benefit Assessment**

<Provide a brief risk benefit assessment. Note that strong justification is needed if the risk outweighs the benefits. State how and where study related injuries are to be treated>

<Example: As stated above, there is minimal risk from the investigational product and study procedures. Study findings shall potentially greatly improve treatment outcomes. The expected benefit outweighs the minimal risk to subjects and thus this study should be supported>

**6. HUMAN SUBJECTS PROTECTION AND ETHICAL ASPECTS**

<State that the study will be conducted in compliance with ethical principles outlined in the Declaration of Helsinki and Malaysian Good Clinical Practice Guideline>

< If potentially vulnerable subjects will be enrolled in the study (for example, pregnant and lactating women, children, prisoners, cognitively impaired and critically ill subjects), include a justification for their inclusion. State how these vulnerable subjects will be protected>

# 6.1 Informed Consent/Assent Process

<State where, when, and process for obtaining informed consent/assent. State how informed consent/assent will be obtained from vulnerable subjects>

<Example: Patients shall be informed of the study during their usual clinic visits. They will be requested to contact investigators if they are interested. An appointment will be made where the patient information sheet will be provided and explained to them. If they are willing to participate, the consent forms will be signed and dated. If they need to, they are allowed to take the information sheet home to consult with their family members, and another day will be arranged for consent>

# 6.2 Privacy and Confidentiality

<State how subjects’ personal data will be kept confidential. State the persons who will have access to the data. State how long after completion of study will the data be stored and whether data will be destroyed after that period of storage. State whether subjects can request access to their personal info and study findings>

<Example: Subject’s names will be kept on a password-protected database and will be linked only with a study identification number for this research. The identification number instead of patient identifiers will be used on subject data sheets. All data will be entered into a computer that is password protected. On completion of study, data in the computer will be copied to CDs and the data in the computer erased. CDs and any hardcopy data will be stored in a locked office of the investigators and maintained for a minimum of three years after the completion of the study. The CDs and data will be destroyed after that period of storage. Subjects will not be allowed to view their personal study data, as the data will be consolidated into a database. Subjects can write to the investigators to request access to study findings. No personal information will be disclosed and subjects will not be identified when the findings of the survey are published>

# 7. POTENTIAL CHALLENGES AND MITIGATION STRATEGIES

# <Identify potential challenges that may arise during the study and propose strategies to address or mitigate these challenges>

<Example: Foreseeable challenges in this study would be lack of human resources (research assistant or admin staff) for the data collection which due to limited financial aid. Hence, this study will be collaborating with University of XXX to use their human resources during the data collection period from 1st March 2020 until 1st March 2021>

# 8. FUNDING OR SPONSORSHIP DISCLOSURE

# <This section is to declare any financial aid or sponsorship that will be received to run this project which includes financial, in-kind, or in the form of materials, drugs, or instruments. State the amount, duration and purpose for the aid received. Include the proof of financial aid or sponsorship if any>

<Example: This project will be receiving financial aid of RM5,000 from Company XYZ at the start of this study for the purpose of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Attached at Appendix X for the proof of financial aid from Company XYZ>

<Example: This project will be using Software ABC from Company EFG throughout the study period from 1st January 2021 until the expected end date 31st July 2024>

# 9. CONFLICT OF INTEREST

<Clearly document any consultative relationship that the principal or co-investigators has with any entity related to the protocol that might be considered an apparent conflict of interest. Depending upon the type of conflicts, these can be managed according to institutional policy>

<Example: The investigators declare that they have no conflict of interest>

**10. APPENDICES**

<Include all the appendices. Compulsory to include Study Flow Chart and Gantt Chart. Also include the questionnaires used. For study that will be receiving financial aid from Sunway Medical Research Fund, the Budget Proposal of the study is mandatory>

**Appendix 1: Study Flow Chart**

<Please revise the flow diagram below to align with your methodology. Ensure that all steps accurately reflect your process and methodology, and update any relevant details to ensure consistency with your research design>

**CONSORT 2020 Flow Diagram**

## Follow-Up

Analysed (n= )
 Excluded from analysis (give reasons) (n= )

## Analysis

Analysed (n= )
 Excluded from analysis (give reasons) (n= )

Lost to follow-up (give reasons) (n= )

Discontinued intervention (give reasons) (n= )

Lost to follow-up (give reasons) (n= )

Discontinued intervention (give reasons) (n= )

## Enrollment

Allocated to intervention (n= )

 Received allocated intervention (n= )

 Did not receive allocated intervention (give reasons) (n= )

## Allocation

Allocated to intervention (n= )

 Received allocated intervention (n= )

 Did not receive allocated intervention (give reasons) (n= )

Randomized (n= )

Excluded (n= )

  Not meeting inclusion criteria (n= )

  Declined to participate (n= )

  Other reasons (n= )

Assessed for eligibility (n= )

**Appendix 2: Study Gantt Chart**

|  |  |  |
| --- | --- | --- |
| Activity | **2024** | **2025** |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 |
| Literature Review |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Ethics Approval  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Data Collection |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Interim Data Analysis |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Final Data Analysis |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Final Result Review |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Report Writing |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Publication |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**<Appendix 3: Budget Proposal** (This section is applicable only if you plan to apply for the Sunway Medical Research Fund)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Description** | **Quantity/Cost (RM)** | **Year 1 (RM)** | **Year 2****(RM)** | **Total****(RM)** |
| Salary and wages for contract personnel |  |  |  |  |
| Travelling expenses and substances (domestic only) |  |  |  |  |
| Rental and hire |  |  |  |  |
| Supply of raw material (i.e., consumables kits) & material for repair and maintenance |  |  |  |  |
| Professional services, hospitality, and other services  |  |  |  |  |
| Small equipment and accessories (including printing and stationary) |  |  |  |  |
| **Total (RM)** |  |  |  |

**< Example of Quotation>**

**Quotation**

**Laboratory Supplies**

**CDE COMPANY**

**Client Information** Date: 1 July 2019

Dr. ABC Quotation Number : 2244

SunMed.

|  |  |  |  |
| --- | --- | --- | --- |
| **Item/Product** | **Quantity** | **RM per unit** | **Total (RM)** |
| Reagent (Biochemistry test) | 100 | 20 | 2000.00 |
| Glucometer | 2 | 180 | 360.00 |
| Test tube | 1000 | 2 | 2000.00 |

Total (RM): **RM 4,600.00**

If you wish to modify the product item, please contact our sales person.

Price includes 6% services tax.

Regards, Confirmed & Acceptance by:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Ms. Melisa Ong Signature and company stamp**

**Sales Manager Name**

**CDE company Date**

<This section is applicable only if you plan to apply for the Sunway Medical Research Fund. Please attach quotation(s) if the budget requested for funding involves materials or equipment to be purchased i.e., reagent, laboratory equipment, test tubes etc.>

<Attached is the quotation for the materials to be purchased or service to be requested

**<Appendix 4: Denmark England Finland (DEF) Questionnaire>**

**11.0 REFERENCES**

<List all the references used.>