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| **I** **ndependent Ethics Committee**  **Ramsay Sime Darby Health Care** | Application to conductResearch |

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| Principal Investigator’s (PI) Name & Stamp |  | | PI Institution | |
|  |  | | Contact No:  Email: | |
| Co Investigators  (If any) |  | | Institution | |
| Study Coordinator(if any) |  | | Contact No |  |
| Title of Project |  | | | |
| NMRR ID |  | | *National Medical Research Registry (NMRR) registration is compulsory for Clinical Trials or Research involving Drugs* | |
| Protocol Number (if available) |  | Current Version Date (if available): | | |
| Purpose of study | Academic requirement (Thesis, Dissertation, Training Requirement)  Independent research work  Multi-institutional or multi-country collaboration  Others (indicate): | | | |

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| Has this project been submitted or is planned for submission to any other ethics committee(s) in Malaysia?  No  Yes:   * If Yes, please provide name and contact details of the Ethics Committee/IRB(s), and indicate the status of the application. * If rejected, state reasons given by that Ethics Committee for its disapproval/rejection or provide a copy of the letter of disapproval/rejection  |  |  |  | | --- | --- | --- | | Ethics Committee  *Name & Address* | Application submission date | Status of application  **A** = Awaiting review  **B** = Full approval  **C** = Conditional approval  **D** = Disapproved/rejected | |  |  |  | |  |  |  | |  |  |  | | |
| Has this proposal been rejected by any IEC/ IRB? | |
| No  Yes: If yes, please provide details for the rejection: | |
| Type of Research | | Clinical research: research conduct primarily in clinical setting involving patients or human volunteers as research subjects  Community research: research conduct primarily in community setting involving patients or human volunteers as research subjects  Others:  **Phase of Study**: Phase I Phase I/II  Phase II Phase III  Phase IV  **Subtype of Research**  Interventional: studies in human beings in which individuals are assigned to receive specific interventions. Subjects may receive diagnostic, therapeutic or other types of interventions. The assignment of the intervention may or may not be random. The individuals are then followed and biomedical and/or health outcomes are assessed  Observational: studies in human beings in which biomedical and/or health outcomes are assessed in a pre-defined group of individuals. Subjects in the study may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the subjects of the study  Retrospective Medical Records Review  Human tissue research Questionnaire surveys  Others (describe the nature of the research below) | |
|  | | This study is initiated by the:  Investigator  Sponsor Company  Source of funding :  Name of Sponsor Company:  Name of CRO (if applicable):  Site: \*  Single Centre /  Multi-centered / International Multi-centered | |
| For Clinical Trials only | | Will the Sponsor named above undertake in writing to indemnify the institution where the research is conducted, the Independent Ethics Committee and the investigators?  Yes No  If you answered YES, provide a letter of indemnification from the Sponsor | |

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| **Research Synopsis**  Full protocol must be attached | *Provide a brief and simple description of your study in less than 500 words. The description must be in plain English suitable for a lay person. Using the following headings: background; objectives / hypotheses / questions; research design; study population, method and technique (e.g. survey, interview, observation, etc) and potential value and significance of the research, and anticipated outcomes* |
| *Please provide summary of the following*  Aims/Purpose  Objectives  Exclusion Criteria  Inclusion Criteria  Interventions  Specific name of intervention under investigation  Primary Endpoint  Safety Monitoring & Withdrawal |  |
| **Study Information** | Targeted Number of Study Subjects/Records globally :       subjects  Targeted Number of Study Subjects/Records in this site :       subjects  Targeted start date in (dd/mm/yyyy):       Targeted completion date (dd/mm/yyyy):    Duration of project/study : |
| Indicate the duration of subject involvement in the research: |
| **Intervention Type**  No intervention | Intervention Type.  Drug  Gene Transfer - including gene transfer and recombinant DNA (e.g., Human nerve growth factor)  Vaccine  Behavior (e.g., Protein and calorie controlled diet; Self-hypnotic relaxation)  Device (e.g., Defibrillators, implantable; Electronic medication reminder system)  Procedure (e.g., Adenoidectomy; Bronchoalveolar lavage)  Others (describe below) |
| If the research involves a study drug, does the study drug or excipients contain porcine or bovine or animal elements?  No  Yes . If yes, please describe further: |
| **Purpose of Clinical trial**  Not applicable | Purpose of trial. Select one.  Treatment: research designed to evaluate one or more interventions for treating a disease, syndrome, or condition  Prevention: research designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition  Diagnosis: research designed to evaluate one or more interventions aimed at identifying a disease or health condition  Educational/Counseling/Training: research designed to assess one or more interventions in an educational, counseling, or training environment  Others (describe below) |
| Allocation  Not applicable | Participant selection. Select one.  Randomized Controlled Trial: participants are assigned to intervention groups by chance  Nonrandomized Trial: participants are expressly assigned to intervention groups  Others (describe below) |
| Masking  Not applicable | Knowledge of intervention assignments. Select one.  Open: no masking is used. All involved know the identity of the intervention assignment.  Single Blind: participants are unaware of the intervention assignment; investigators are aware.  Double Blind: both participants and investigators are unaware of the intervention assignment  Others (describe below) |
| **Control treatment**  Not applicable | Nature of the intervention control. Select one.  Placebo: participants may receive only placebo throughout the course of the research  Active: participants may receive some form of treatment (e.g., standard treatment) in place of the intervention under investigation  Uncontrolled: no controls are used  Historical: the control consists of results from past studies  Dose Comparison: participants may receive one of several doses of the intervention  Others (describe below) |
| **Assignments**  Not applicable | Study configuration and intervention assignments. Select one.  Single Group: all participants receive the same intervention throughout the research  Parallel: participants receive an intervention throughout the research  Cross-over: participants may receive different interventions sequentially during the research.  Factorial: participants may receive no intervention, some intervention, or multiple interventions simultaneously  Expanded Access: includes treatment IND research  Others (describe below) |
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Risk & Benefits

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| **Risks and Precautions** | *Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests* |
|  | |  |  |  | | --- | --- | --- | |  | Risk Category |  | | 1 | Research not involving greater than minimal risk  Low – innocuous procedures e.g. phlebotomy; no therapeutic agent. |  | | 2 | Research involving greater than minimal risk but presenting the prospect of direct benefit to the participant  Medium – “safe” therapeutic agent.  *Note: Chemotherapy side effects will be expected* |  | | 3 | Research involving greater than minimal risk, presenting NO prospect of direct benefit, but likely to yield generalizable knowledge about the participant’s condition.  Please note that all four of the following conditions must be met in order to qualify for this category:   1. The risk represents a minor increase over minimal risk. 2. The intervention/procedure presents an experience reasonably commensurate with the subject’s expected medical, dental, psychological, social, or educational situations. 3. Generalizable knowledge of vital importance for the understanding or amelioration of the subject’s condition will likely be derived. 4. Provisions for obtaining the assent of children and permission of parents or guardians are appropriately planned.   Or  High – Includes vulnerable subjects, along with therapy with chemo, gene, antibody, or toxic drug and risky procedures, as well as investigational drugs not yet approved by the FDA or DCA, |  | |
| Could participation in this research adversely affect the subject(s)? Yes  No *If you answered YES, how will this research adversely affect the subject? What measures will be in place to deal with these anticipated adverse effects?* | |
| Is there a prospect of direct benefit to subjects? Yes  No*(A research benefit is considered something of health-related, psychosocial or other value to an individual subject, or something that will contribute to the acquisition of generalisable knowledge. Money or other compensation for participation in research is not considered to be a benefit, but rather compensation for research-related inconveniences.)*If you answered NO, tick the appropriate category below:  |  |  | | --- | --- | | Involves no prospect of direct benefit to subject but likely to yield generalisable knowledge about subject’s condition |  | | Involves no prospect of direct benefit to subject but likely to yield generalisable knowledge to further society’s understanding of the condition under study |  | | Involves no prospect of direct benefit to subject |  | | |

**Study Population**

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| Study population: | Normal volunteers  Disease: (specify) | |
| Does this study target a vulnerable population(s) as the primary research population? | | Yes  No |
| *If yes, tick the appropriate boxes:*  patients with incurable diseases,  persons in nursing homes, unemployed or impoverished persons,  patients in emergency situations, ethnic minority groups, homeless persons,  refugees,  minors,  hose incapable of giving consent  If yes, please specify and explain the special attention which will be placed to vulnerable research participants: | | |
| Characteristics Of Participants | Age Range:  0 -17 yrs  18 - 44 yrs  45 - 65 yrs  > 66 yrs  Pediatric  None  < 1 yr  1-3 yrs  4 -14 yrs  Others: | |

**Ethical Issues & Consideration**

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| *Does this project conform to the Declaration of Helsinki/Malaysian Good Clinical Practice (GCP) Guidelines?*   *Yes*   *No* |
| Significance of the study, and reason for using human subjects.  *(Describe how this study is considered necessary, and reason why the study has to be carried out by using human subjects*) |
| Describe informed consent process/method of invitation the participants to participate in the research, such as personal contact, referral from other(s), brochure, and announcement, etc.  *(Describe the subject recruitment strategies you will use for each group of subjects. Explain who will be recruiting subjects and how subjects will be approached to participate in the study. For example, the investigator's nurse may approach patients to ask if they are interested in the study. Provide examples of the flyers, advertising, announcements, etc., that you will use).* |
| Benefits of the study.  *(Describe the anticipated benefits of this research for individual subjects in each subject group, and society. If none, state “None.”)* |
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**Privacy and confidentiality:**

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| 1. Research Study Involves  |  |  | | --- | --- | | Direct Identifiers (Patient identified by name/MRN) |  | | Indirect Identifiers/Coded (Patient identified after break of code) |  | | Completely Anonymised /Delinked (Patient cannot identified) |  |   2. Confidentialhandling of data by staff Yes  No |
| 1. What precautions will be used to maintain the confidentiality of identifiable health information?   Records will be kept in a secured location and only accessible to personnel involved in the study.  Computer based files will only be made available to personnel involved in the study through the use of access privileges and passwords.  Before accessing to any study-related information, personnel have to sign statements agreeing to protect the security and confidentiality of identifiable health information.  Whenever feasible, identifiers will be removed from study-related information.  Others, specify |

DECLARATION BY INVESTIGATOR (S)

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| 1. I / We\* are applying for ethical approval to conduct this research project. If approval is granted, it will be undertaken in accordance with this application and other relevant laws, regulations and Good Clinical practice guidelines of Malaysia. 2. I / We\* declare that the information provided in this application is accurate. 3. I will not initiate this study until I receive written notification of IEC approval and regulatory authority approval (if applicable). 4. I will not initiate any change in protocol without prior written approval from IEC except when it is necessary to reduce or eliminate immediate risk to the Study Participant. Thereafter, I will submit the proposed amendment to the IEC and other relevant authority for approval. 5. I will promptly report any unexpected or serious adverse events, unanticipated problems or incidents that may occur in the course of this study. 6. I will maintain all relevant documents and recognize that the IEC staff and regulatory authorities may inspect these records. 7. I understand that failure to comply with all applicable regulations, institutional and IEC policies and requirements may result in the suspension or termination of this study. 8. I declare that there are no conflicting interests for any of the research personnel participating in this research study. ***(Important: Should you or any of the research personnel have any conflicting interest in this research study, please complete Annex B – Conflict of Interest Declaration Form for each individual having the conflict)*** |

*This portion must be signed by Principal Investigators and Co Investigators*

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| --- | --- |
| Name of applicant    Investigator’s Name & Stamp | Signature of applicant:  Date: |
| Name of applicant    Investigator’s Name & Stamp | Signature of applicant:  Date: |
| Name of applicant    Investigator’s Name & Stamp | Signature of applicant:  Date: |
| Name of applicant    Investigator’s Name & Stamp | Signature of applicant:  Date: |
| Name of applicant    Investigator’s Name & Stamp | Signature of applicant:  Date: |

# Checklist for Research involving Drugs

## Please send 10 copies of the completed application forms with supporting documents and a set of soft copies to

## Independent Ethics Committee Ramsay Sime Darby Health Care (IEC RSDHC)

## Secretariat c/o Clinical Research Office,

## Ground Floor Outpatient Centre

## Subang Jaya Medical Centre,

## No 1, SS12/1A, 47500 Subang Jaya, Selangor Darul Ehsan

## Tel: 03- 56391987

## Please use the submission checklist to ensure the submission is complete.

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* A one-time application fee of RM 1,500 per research study is charged for the services of IEC to review sponsored research.
* Application will only be processed upon receipt of full payment.
* Payment is to be made by cheque or bank transfer.
* Please make the cheque payable/ bank transfer to:

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| --- | --- | --- | --- |
| **Beneficiary Name** | **Bank Name** | **Account No** | **Swift Code** |
| RSD Hospitals Sdn Bhd-SJMC | CITIBANK BERHAD | 0116733013 | CITIMYKL |
| RSD Hospitals Sdn Bhd-SJMC | CIMB BANK BERHAD | 8007337597 | CIBBMYKL |

* Submit the cheque/bank transaction slip together with your applications. Kindly attach the following information with the cheque/ bank transaction slip:

🞎 Full protocol title & No

🞎 PI’s name, department and institution

🞎 Sponsor’s contact person (name and emailing address)

* It is the prerogative of IEC to waive this fee for non-commercial and non-sponsored research