**PARKWAY INDEPENDENT ETHICS COMMITTEE**

**APPLICATION FORM**

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| **I. Basic Information** | | |
| **Full Protocol Title:** | | |
| Text Field | | |
| Protocol Number : | | |
| Text Field | | |
| **Study Team Members:**  ***Note:*** *Each study site must have a Site Principal Investigator (PI) who is responsible for the conduct of the study in his/her site. One of the Site PI should be appointed as the Coordinating Principal Investigator who will be the primary contact person who corresponds with PIEC for matters related to this study. All investigators and collaborators who have a responsibility for the consent process and/or direct data collection for this study should be listed below. Multiple copies of this page may be submitted as necessary.* | | |
| |  |  |  |  | | --- | --- | --- | --- | | **Title** | **Full Name** | **Study Role** | **Study Site** | |  | Text Field |  | Text Field | |  | Text Field |  | Text Field | |  | Text Field |  | Text Field | |  | Text Field |  | Text Field | |  | Text Field |  | Text Field | | | |
| Funding Source: | | |
| If Other/Pharmaceutical Company, please specify: Text Field | | |
| ***Note:*** *For industry-sponsored study, please complete and attach Annex D.* | | |
| Nature of Study: | | Phase of Clinical Trial (for drugs and biologics): |
| If Clinical Trial, please specify: | |  |
| Research May Involve: | | |
| |  |  | | --- | --- | | Pregnant Women, Fetuses or Neonates *(Attach Annex F)* | Outpatients | | Minors (Age < 21 yrs and who has never been married.)*(Attach Annex G)* | Inpatients | | Persons Lacking Mental Capacity – Please specify type: | Healthy Volunteers | | Others - Please specify type: | Non-English speaking subjects | | | |
| Study Site details: | | |
| Single-Centre Study | Multi-Centre Study:- No. of local sites:       No. of overseas sites: | |
| Other Study Sites: | SingHealth  NHG  Others: | |
| Has this application been previously rejected by any IRB? | | |
| No  Yes If yes, please provide details for the rejection: | | |
| Is this a US FDA IND / IDE study? | | |
| No  Yes  IND Study. Please provide the IND number:  IDE Study. Please provide the IDE number: | | |

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| **II. Declaration of the Principal Investigator** | | | | |
| ***Note:*** *– For multi-centre studies under the oversight of PIEC, the Coordinating PI and each Site PI must sign this page. Multiple copies of this page may be submitted as necessary.* | | | | |
| Protocol Title: Text Field  The information provided in this form is correct.   1. I will not initiate this study until I receive written approval from the PIEC and regulatory authority (if applicable). 2. I will not initiate any change in the study protocol without prior written approval from the PIEC except when it is necessary to reduce or eliminate immediate risk to the study participant. Thereafter, I will submit the proposed amendment to the PIEC and other relevant authority for approval. 3. I will promptly report any unanticipated problems involving risks to study participants or others (UPIRTSO) that may occur in the course of this study. 4. I will maintain all relevant documents and recognize that the PIEC staff and regulatory authorities may inspect these records. 5. I understand that failure to comply with all applicable regulations, institutional and PIEC policies and requirements may result in the suspension or termination of this study. 6. I declare that there are no existing and potential conflict of interest for any of the research personnel participating in this research study. **(*Important: All investigators and research staff involved in this research are required to complete Annex B – Conflict of Interest Declaration Form)*** 7. I declare that I have not been involved in any study that is suspended / terminated by an IRB or regulatory authority due to misconduct / non-compliance. 8. If the proposed research is regulated under the Human Biomedical Research Act, I understand that I am responsible to ensure that necessary contractual or other arrangements has been made with a research institution for the proposed research to be conducted under the supervision and control of the research institution.   **Remarks (if any):**  Text Field | | | | |
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| *Principal Investigator’s Signature*  *\*PI must be based in Singapore.* | | *Date* | |
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| *Full Name:* | Text Field | *Designation:* | Text Field |
| *Site Name:* | Text Field | *Email address:* | Text Field |
| *Telephone:* | Text Field | *Fax:* | Text Field |
| *\*Site Address:* | Text Field | | |
| *\*Clinics/Research Centers of different branches are considered different sites. Each site must have a Site-PI.* | | | |

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| **III. Study Team Members’ Endorsements** |
| *All co-investigators and collaborators who have a responsibility for consent process or direct data collection for this study should be listed below. Multiple copies of this form may be submitted as necessary. (i.e. All collaborators/co–investigators need not sign on the same form). Each member must sign the Annex B – Conflict of Interest Declaration Form.* |

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| **IV. Study Staff List** | | | |
| *All study staff who are delegated a task in the study should be listed below. Multiple copies of this form may be submitted as necessary. No signature is required. Each staff must sign the Annex B – Conflict of Interest Declaration Form.* | | | |
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| **V. Abstract of Research Proposal** |
| *In no more than 300 words, include a brief description of (1) Aims, (2) Methodology (3) Importance of proposed research to science and/or medicine and (4) Potential benefits and risks. The abstract must be self-contained so that it can serve as a succinct and accurate description of the application when separated from it. Please use lay terms. If this is not possible, the technical and medical terms should be explained in simple language.* |
| Text Field |

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| **VI. Research Details** |
| *Organize details of the research proposal under the following headings (in no more than 7 pages).* |
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| **1. Specific Aims & Hypothesis** |
| *State concisely and realistically what the research described in this application is intended to accomplish and/or what hypothesis is to be tested.*  Text Field |
| **2. Introduction** |
| *a) Briefly describe the background to the current study proposal, critically evaluate the existing knowledge and specifically identify the gaps that the proposed study is intended to fill.*  Text Field |
| *b) State concisely the importance of the research described in this application by relating the specific aims to the long term objectives.*  Text Field |
| *c) Relevant references (please submit copies of at least two relevant papers)*  Text Field |
| **3. Preliminary Studies / Progress Reports** |
| *Provide an account of preliminary studies (if any) pertinent to the application~~s~~*  Text Field |
| **4. Methodology** |
| *a) Discuss in detail the experimental design and procedures to be used to accomplish the specific aims of the study.*  Text Field |
| *b) Describe the protocol(s) to be used. Include information of the study drug / device /surgical procedures that will be used in the trial. If it is a placebo-controlled trial, please complete and attach Annex A.*  Text Field |
| *c) Include details on sample size and power calculation and the means by which data will be analyzed and interpreted.*  Text Field |
| *d) List all activities that are carried out as part of research in this study. Please state or list all procedures involved in this research study and attach the data collection form (if any).*  Text Field |
| *e) List all activities that are performed for routine diagnostic or standard care of the participant.*  Text Field |
| *f) Please describe the study visits (frequency and procedures involved). For studies with multiple visits, please attach study schedule.*  Text Field |
| *g) If the study involves the use of study drug / device, describe how you plan to ensure that investigators are trained in the management (receipt, handling, storage, utilization, and disposal) of the study drug/device. Please submit the Investigator’s Brochure or local product information sheet/leaflet as applicable.*  Text Field |
| *h) Please describe how you plan to ensure that the study drug / device would be used only by investigators, and only in study participants.*  Text Field |
| *i) Will any biological materials be collected for the use of this study? If ‘yes’, please complete and attach Annex C.*  Text Field |
| *j) Describe the alternative or standard care used at your medical clinic to treat or diagnose this condition.*  Text Field |
| *k) What are the anticipated benefits and risks to study participants in this research?*  Text Field |
| l) Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims.  Text Field |
| *m) Will any part of the study procedures be recorded on audiotape, film/video, or other electronic medium?*  *Yes*  *No*  If ‘Yes’, Please describe the contents of the recording? What is the medium used for recording? Explain how the recorded information will be stored and used in the study? For how long and where will the recording medium be retained? Who will have access and how will access be controlled and monitored? How will the recording medium be disposed?  Text Field |
| **5. Characteristics of Target Study Participants** |
| *If the target Study Participants include these vulnerable populations, please complete and attach the relevant Annexes to the Application Form:-*   * ***Annex F:*** *Pregnant Women, Fetuses and Neonates* * ***Annex G:*** *Minors (Persons under the age of 21 years)* |
| a) What is the number of Study Participants to be enrolled / number of biological samples / medical records to be collected? Give a breakdown by institution for multi-centre studies within Singapore. Please also include those sites that are not under the oversight of PIEC.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Institution** | **Target Enrolment Number\***  (Exclude screen failures) | **No of Adult Males** | **No of Adult Females** | **No of Children**  (Persons under the age of 21 years) | | Text Field |  |  |  |  | | Text Field |  |  |  |  | | Text Field |  |  |  |  | | Text Field |  |  |  |  | | Text Field |  |  |  |  | | Text Field |  |  |  |  | | Text Field |  |  |  |  | | Text Field |  |  |  |  |   \* *If the study only involves the collection of biological samples and/or collection of data from medical records, please indicate the number of samples / medical records to be collected in lieu of enrolment number.*  Study Participants’ Lower Age Limit:  Study Participants’ Upper Age Limit:  Total number of Study Participants targeted for enrollment worldwide (for international studies):  b) Are there any recruitment restrictions based on race or gender of the Participant?  Yes  No  If ‘ Yes’, Please provide rationales:-  Text Field c) List the Inclusion criteria Text Field  *d) List the Exclusion criteria*  Text Field  e) Do the potential subjects have a dependent relationship with the study team? E.g. doctor-patient, employee-employer, student-teacher etc. If Study Participants are patients under the care of the investigators, please answer ‘Yes’.  Yes  No  Not applicable  If ‘Yes’, please describe how the study team will manage the dependent relationship to prevent coercion or undue influence. -  Text Field  f) Will any vulnerable Study Participants (e.g. Pregnant Women, Fetuses & Neonates, Minors (Persons under the age of 21 years, Cognitively Impaired individuals, Mentally Disabled Individuals etc.) be recruited in this research study?  Yes  No    If ‘Yes’, please explain why the research must recruit this group of population and describe measures in place to protect their rights and welfare.  Text Field |
| **6. Informed Consent Process and Consent Document** |
| *Please note that PIEC requires that written informed consent should be obtained from all research participants and documented prior to their participation in any research, unless the PIEC approves the waiver of informed consent or waiver of documentation of informed consent. To request for waiver of informed consent, please complete and attach Annex E.* |
| *Please describe the consent procedure.*  *a) When will consent be taken?*  Text Field  *b) Where will consent be taken and what procedures will be followed? E.g. face-to-face consent interview, virtual consent or other methods.*  Text Field  *c) Who will conduct the consent process and the language used by those obtaining consent?*  Text Field  *d) Who will provide consent or permission and the language understood by the prospective participant or the legally authorized representative?*  Text Field  *e) Describe the circumstances where obtaining informed consent from a potential Study Participant is not possible and informed consent will be taken from the legally acceptable representative (including spouse, parent, and guardian)?*  Text Field  *f) Any waiting period between informing the prospective participant and obtaining consent? Please ensure ample time is given to potential subjects to decide on study participation.*  Text Field  *g) How will consent be documented i.e. paper-based? How will study team ensure that a signed copy is given to all subjects?*  Text Field  *h) Describe provisions to protect the privacy interests of Study Participants, where “privacy interests” refer to interests of individuals to be left alone, free from intrusion and comfort with the proposed settings.*  Text Field  *i) Besides the Consent document, will any other materials or documents be used to explain the study to potential Study Participants? (E.g. scripts, handouts, brochures, videos, logs, etc.). If yes, please submit a copy of the material/document.*  Text Field |
| **7. Recruitment Process** |
| *a) How will the potential subjects be identified? E.g. Referral by attending healthcare professional, Patient of study team, Database, Medical Records, or Advertisement etc.*  Text Field  *b) If participants are chosen from medical records, how will you obtain the names and NRIC of potential Study Participants?*  Text Field  *c) Will any advertising /recruitment materials be used? E.g. Posters, brochures, slide deck, advertisement in newspaper/magazines/publications, advertisement on radio/TV/websites, letter of invitation to potential research participants, letter to doctors requesting for referrals etc. Please also describe where and how will the recruitment materials be used. Please submit a copy of the recruitment materials.*  Text Field  *d) Will any other recruitment strategies be used? E.g. Talks/Events/Public forum at hospitals or public places, use of recruitment agency, online portal etc. Please provide details.*  Text Field |
| **8. Data And Safety Monitoring** |
| For studies that are less than minimal risk or investigator-initiated study, the investigator(s) could perform the data and safety monitoring.  If the research involves more than minimal risks to Study Participants, please provide details on the Data And Safety Monitoring Plan (DSMP) of the research.  *a) Who performs the data and safety monitoring? If there is a Data Safety Monitoring Board (DSMB), please provide the charter of the DSMB.*  Text Field  *b) When (i.e. frequency of review) and what safety data (e.g. adverse events / serious adverse events) will be monitored?*  Text Field  *c) When and how is data integrity monitored to ensure study data is authentic, accurate and complete?*  Text Field  *d) What are the criteria for stopping or suspending the research?*  Text Field  *e) How will the outcome of data and safety monitoring be communicated to other sites? (for multi-centre studies only)*  Text Field |
| **9. Research Data Confidentiality** |
| *In general, to protect Study Participant’s privacy, research data should be coded, and the links between the Participant’s identifiers and the codes should be stored separately from the research data.*  *a) Will coded research data be sent to the sponsor, and no research database will be created at study site?*  *Yes,* *If ‘Yes’, please skip this question and go to Section 10 – Timelines.*  *No, If ‘No’, please answer the following questions:-*  *b) Describe where the research data will be stored? (i.e.: network or Stand-alone PC and the physical location)*  Text Field  *c) Who will have access to the research data and how will access to the research data be controlled and monitored?*  Text Field  *d) Are there any research data sharing agreements with individuals or entities outside the study site, to release and share research data collected?*  *No*  *Yes, If yes, please describe the agreement*  Text Field  *e) Describe what will happen to the research data when the study is completed.*  Text Field  *f) Are there any other measures in place to protect the confidentiality of the research data?*  Text Field |
| **10. Timelines** |
| *a) What are the estimated start and end dates of the study?*  *Note: The start date should be after the study has obtained ethics approval and regulatory approval (if applicable).*  Start Date:       End Date: |
| *b) What is the recruitment period? Indicate the duration of participants’ involvement in the research study. This includes the time from the screening procedures till completion of active follow-up.*  Text Field |
| **11. Financial Aspects** |
| ***Note: Please note that it is against the MOH policy on no charging of research subjects for participants to pay for research-related costs/procedures. The PI should ensure that funding is available to cover these costs.***  *a) Who will be responsible for research related costs? List the research cost that will be borne by the study sponsor or study site (for investigator-initiated study).*  Text Field  *Total amount of grant/fund: $*  *b) Will subject incur any additional expenses due to study participation? If yes, please elaborate.*  Text Field  *c) If this study has a Study Grant, please answer the following questions.*  *i) Has the study grant been awarded?*  *Pending approval*  *Yes. If ‘Yes’, please submit a copy of the grant approval letter.*   1. *Which grant exercise was this submitted to? (enter Grant Submission Deadline date)*   Text Field   1. *For* ***approved grant applications*** *(including United States Department of Health and Human Services (DHHS) approved studies), please submit the protocol and consent document (if any) approved by the grant body.*   *Are the Protocol and Consent documents approved by the grant body, identical to the information that has been submitted in this application?*  *Yes*  *No. If ‘No’, please provide details of the differences:*  Text Field |
| d) Will the Study Participants receive any financial payment/incentive for participation e.g. transport allowance?  *Yes  No*  *If ‘Yes’, please elaborate the mode of payment and payment schedule*.  Text Field  e) Who will be responsible for the payment and compensation of injury or illness arising from participation in the research study?  Note: The PI should ensure that insurance coverage is available to provide payment and compensation to research participants for any injury or illness arising from their participation in the study.  Text Field |

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| **12. Application Checklist:** | |
| **Attached?** | **Document** |
|  | Study Protocol  *Note: The PIEC Application form cannot be used to replace a study protocol.* |
|  | Approved Grant Application *(including DHHS approved Study Protocol and Sample Consent Form, if one exists)* |
|  | Participant Information Sheet and Consent Form |
|  | Investigator’s CV (for ALL investigators) |
|  | Relevant Training Certificates / GCP certificate / CITI certificate (for ALL investigators) |
|  | Investigator’s Brochure / Product Leaflet |
|  | Survey Forms / Questionnaires / Diary Card |
|  | Data Collection Form / Case Report Form |
|  | Recruitment Materials (e.g. Posters, News Advertisement) |
|  | Letter of Invitation to Patients |
|  | Relevant Publications |
|  | Cheque Payment for Review Fee |
|  | Participant Payment Details + |
|  | Participant Compensation Details + |
|  | Financial Agreement (optional) |
|  | Certificate of Insurance (Applicable to all clinical trials) |
|  | Annex A – Placebo Usage |
|  | Annex B – Conflict of Interest Declaration Form (For all study team members and study staff) |
|  | Annex C – Biological Materials Storage |
|  | Annex D – Industry Sponsored Studies |
|  | Annex E – Waiver of Informed Consent |
|  | Annex F – Research involving Pregnant Women, Foetuses and Neonates |
|  | Annex G – Research involving Minors (*Persons under the age of 21 years and who has never been married.)* |
|  | Annex H – Indemnity Form (For all applications) |
|  | Any other materials/documents?Please list here:-  Text Field |

+ If information is not included in the protocol / application form

**~ End of Application Form ~**