ACMS IRB Application Form

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| **Submission Guidelines** |
| 1. Original handwritten or electronic signatures from all parties (e.g. Principal Investigator (PI), Co-Investigator (Co-I) and CEO) are required. 2. The Principal Investigator (PI) should ensure that the application form and all supporting documents are duly completed and submitted. Applications will only be processed by the ACMS IRB when all documents are in good order. 3. The right footer must indicate the version number and date (e.g. Version 1 dated dd/mmm/yyyy) of the document being submitted. For the first submission, the file name should be in the following format “ACMS IRB Appln V1 [YYYY-MMM-DD] ([PI’s Institution Initials])” (e.g. **“ACMS IRB Appln V1 2019-JAN-01 (SNH)”**). 4. When completing the form, please remove this page of the Submission Guidelines and text in yellow highlight. 5. **Text formatting\*:**  * Headings : Arial, font size 12, Bold, All caps * Sub-headings : Arial, font size 11, Bold * Text (Description) : Arial, font size 11 * Line spacing : 1.0  |  |  | | --- | --- | | **Document** | **Format** | | IRB Application Form | Word (.docx) AND  PDF (.pdf) (with handwritten or electronic signatures) | | * Participant Information Sheet and Consent Form (if applicable, for studies that require consent) * Supporting documents (if applicable):   + Questionnaires / Survey Forms / Interview Guides   + List of variables to be extracted from medical records database | Word (.docx) | | All other supporting documents (if applicable) (e.g. CITI certificates and CVs of all PIs and Co-Is, copy of grant award letter, recruitment flyers) | PDF (.pdf) |  1. **Softcopy submission**   Email the soft copy of the completed application form and requisite supporting documents (as stated above) to: [research@academycms.org](mailto:research@academycms.org)   1. **Hardcopy submission**   The original signed hard copy of application form and supporting documents (CVs of PI, Co-I and Collaborators) should be mailed to:  **Secretariat of ACMS-IRB**  **Academy of Chinese Medicine, Singapore**  **705 Serangoon Road Singapore 328127**   1. For changes in the protocol, ACMS-IRB should be informed within **7 working days**. |

**Section A: Basic Study Information**

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| **Study Title:** | | |
| **Simplified Title:** | | |
| **A1. Principal Investigator (PI) (Applicant)** | | |
| |  |  |  |  | | --- | --- | --- | --- | | **Name** | **Institution** | **Department** | **Designation** | |  |  |  |  | | | |
| **A2. Study Team Members** | | |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Name** | **Study Role (Co-Investigator / Collaborator)** | **Institution** | **Designation** | **Involved in Informed Consent** | |  |  |  |  | ☐ Yes ☐No | |  |  |  |  | ☐ Yes ☐No | |  |  |  |  | ☐ Yes ☐No | |  |  |  |  | ☐ Yes ☐No | |  |  |  |  | ☐ Yes ☐No | |  |  |  |  | ☐ Yes ☐No |   Please attach the following documents supporting the study team members’ qualifications.  i. CV  CV is to be provided and appended at the end of the application form. Please ensure that the information in the CV is accurate and up to date (updated within last 2 years).  The IRB will use the information contained here to assess the qualifications of the Principal Investigator and Study Team Members who will carry out the Study as described in this Application.  ii. The PI, Co-PI and study team members are required to provide their CITI completion report and the PI is also required to provide his/her SGGCP certificate.  **Involved in Informed Consent**  This section requires indication of whether the respective study team members are involved in informed consent.  Only Study Team Members or research assistants who have been delegated by the Principal Investigator can obtain consent from the participants. This should be indicated. It is the responsibility of the Principal Investigator to ensure that the Study Team Members who are delegated to obtain consent have received proper training.  The delegated Study Team Member should also be appropriately qualified to adequately answer questions from potential participants. For clinical trials where a medical opinion is required, a medically trained Study Team Member should obtain the informed consent so that the participant can have his/her questions adequately answered.  Only Study Team Members who have been properly trained to obtain consent and designated with the responsibility of taking informed consent from research participants can obtain consent.  Informed Consent discussions should be conducted by the Principal Investigator, Co-Investigator or a member of the Study Team Member who is listed in the AMCS-IRB Application Form as the designated person for conducting the Informed Consent discussion. Any change to study staff should be submitted to ACMS-IRB for review and approval.  • Informed Consent must be presented in a language understood by the participant. | | |
| **A3. Study Sites**  Name all sites where data collection will take place. | | |
| Name of site(s)  **1.**  **2.** | | |
| **A4. Submissions To Other IRBs** | | |
| **Has this study been submitted to another IRB? Please furnish the details below if applicable.**  ☐ Not applicable   |  |  |  |  | | --- | --- | --- | --- | | **No.** | **Name of IRB** | **Date of Submission** | **Current Status** | | **1** |  |  | ☐ Pending ☐ Withdrawn  ☐ Rejected, please state reasons: \_\_\_\_\_\_\_\_\_ | | **2** |  |  | ☐ Pending ☐ Withdrawn  ☐ Rejected, please state reasons: \_\_\_\_\_\_\_\_\_ | | | |
| **A5. Source of Funding**  Is this study receiving or due to receive funding from other sources? | | |
| **☐** **Grants**  (\*If grant application has been approved, please attach approved grant proposal and supporting documents) | Grant agency: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Grant name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Amount of funding: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Duration of funding: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Status of funding: **☐** Approved **☐** Pending **☐** Not applicable | |
| **☐** **Sponsors** | Sponsor agency: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| **☐** **Others** | Please specify details: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| **☐** **No funding** | | |
| **A6. Study Specialty** | | |
| **☐** A) Internal Medicine  **☐** B) Gynaecology  **☐** C) Paediatrics  **☐** D) Geriatrics  **☐** E) Dermatology  **☐** F) Acupuncture and Tuina  **☐** G) Others, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| **A7. Nature of Research** (select one category that best describes the research activities) | | |
| **☐** Questionnaire/Survey/Interview  Choose this if your research involves administering questionnaires/surveys/interviews. This type of research may also include a medical records review component.  **☐** Medical Records Review  Choose this if your research involves the collection of data for a specific research project by review of medical records including results of routine diagnostic tests performed for standard clinical purposes. The data collection could be done prospectively and/or retrospectively.  **☐** Others. Please Specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| **A7. Study Participants** | | |
| Please check all categories of participants that apply: | | |
| **☐** Healthy Adults  **☐** Outpatients  **☐** Inpatients  **☐** Children (under 21 years old)  **☐** Pregnant Women | | **☐** Cognitively Impaired Persons  **☐** Elderly (60 years and above)  **☐** Persons with disabilities. Please specify: \_\_\_\_\_\_\_  **☐** Persons with mental health issues  **☐** People who are HIV-positive |
| Please fill up the form on research involving Pregnant Women, Foetuses and Neonates,  or Child/Participant Assessment Form if your research involves any of the above. | | |
| **A8. Risk Assessment** | | |
| This proposed study:   |  |  |  | | --- | --- | --- | | **Risks:** | **Yes** | **No** | | 1. Is of minimal risk\* to the research participants. | ☐ | ☐ | | 1. Does not place the research participants at risk of criminal or civil liability and is not damaging to the research participants' financial standing, employability, or reputation if their responses are disclosed outside the research study. | ☐ | ☐ | | 1. Involves no physical, psychological or economic harm to research participants. | ☐ | ☐ | | 1. Does not involve vulnerable populations (e.g. children, prisoners, pregnant women, non-healthy volunteers, cognitively impaired etc.). | ☐ | ☐ | | 1. Does not touch on sensitive topics (including but not limited to illegal conduct, racism, politics, sexual behaviour, religious views). | ☐ | ☐ |   \* Minimal risk: where the probability and magnitude of harm or discomfort anticipated in the research study 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. | | |

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| **A9. Determination of Human Biomedical Research** |
| |  |  |  |  | | --- | --- | --- | --- | | **Does this study fall under the Human Biomedical Research Act?** | | | | |  |  |  | | | **Is the purpose of the research to study:** |  | **Does the research involve any of the activities below?** | | | ☐ the prevention, prognostication, diagnosis or alleviation of any disease, disorder or injury affecting the human body; |  | ☐ Subjecting any individual (including staff) to any intervention (including any willful act or omission) that has a physical, mental or psychological effect (whether temporary or permanent) on the body of the individual; | | | OR |  | OR | | | ☐ the performance or endurance of human individuals; | If **YES** | ☐ Use of individually-identifiable human biological material; | | | OR |  | OR | | | ☐ the restoration, maintenance or promotion of the aesthetic appearance of human individuals through clinical procedures or techniques. |  | ☐ Use of individually-identifiable health information. | | | If **NO,** |  | If **NO,** | If **YES,** | | **☐ Non-HBR** |  | **☐ Non-HBR** | **☐ HBR** | |

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# Section B: Declarations

Does the Principal Investigator or any Study Team Member have any potential conflict of interest? The Declaration is also for the immediate family members of the Principal Investigator and Study Team Members listed below.

All Study Team Members must complete and submit their Declarations as part of this application. The Principal Investigator is responsible for checking and ensuring that accurate information is submitted to the IRB.

The Conflict-of-Interest Declaration Section must be submitted to the IRB via study amendments if any of the circumstances relevant described herein change during the conduct of the research.

A conflicting interest can be broadly defined to refer to any interest of the investigator or immediate family (includes spouse, children, parent(s) and sibling(s)) that competes with the investigator’s obligation to protect the rights and welfare of research participants.

Financial Interest means anything of monetary value, including but not limited to, salary or payments for services (e.g. consulting fees or honoraria); equity interests (e.g. stocks, stock options or other ownership interests); intellectual property rights (e.g. patents, copyrights and royalties from such rights), and board or executive relationships.

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| **B1. Principal Investigator’s Declaration** |
| The information provided in this form is true.   1. I will not initiate this research until I receive written notification of ACMS IRB approval and any other approval from relevant regulatory authorities (local/overseas) (if applicable). 2. I will not initiate any change in protocol without prior written approval from ACMS IRB except when it is necessary to reduce or eliminate risk to the participant. Thereafter, I will submit the proposed amendment to ACMS IRB and all applicable regulatory authorities for approval. 3. I will promptly report any unexpected and/or serious adverse events, unanticipated problems and/or incidents that may occur in the course of this research. 4. I will maintain all relevant documents and understand that the ACMS IRB staff and regulatory authorities may inspect these records. 5. I understand that failure to comply with all applicable regulations, institutional and ACMS IRB policies and requirements may result in the suspension or termination of this research. 6. I declare that there is no existing or potential conflict of interest for any of the investigators participating in this research.   **Financial Conflicts of Interest (FCOI) Declaration**  I declare that:   1. In the past 12 months, I and/or my immediate family have not received compensation by a commercial sponsor(s) of research study(s) in which the value of compensation could be affected by study(s) outcome(s). 2. In the past 12 months, I and/or my immediate family have not received proprietary interest in tested product(s) including, but not limited to, a patent, trademark, copyright or licensing agreement. 3. In the past 12 months, I and/or my immediate family have not received equity interest from a commercial sponsor of my research study(s), i.e., any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices. 4. In the past 12 months, I and/or my immediate family have not received equity interest from a commercial sponsor of my research study(s)where the commercial sponsor is a publicly held company and the interest exceeds $50,000 in value. 5. In the past 12 months, I and/or my immediate family have not received significant payments related to research study of other sorts.   **By signing this declaration, you confirm that you have read, understood and accept the Principal Investigator's Declaration.**  Remarks (if any):   |  |  | | --- | --- | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_ | | Signature of Principal Investigator | Date | | Phone: Fax:  Mailing Address: | | | Email: | | |
| **\*Please state the name and email address of the person(s) to copy to in the IRB’s acknowledgement email. If no name(s) is listed, the IRB Secretariat will only correspond with the PI.**  1.  2. |
| **B2. List of Co-Investigators**  All co-investigators who have a responsibility for the consent process or direct data collection for this research should be listed below. Multiple copies of this form may be submitted as necessary. All co–investigators need not sign on the same form. |
| Name: Email:  Position: Phone:  Department: Fax:  Institution:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Co-Investigator Date |
| Name: Email:  Position: Phone:  Department: Fax:  Institution:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Co-Investigator Date |
| Name: Email:  Position: Phone:  Department: Fax:  Institution:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Co-Investigator Date |

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| **B3. Declaration by CEO\***  Your research must be approved by the CEO or designate of the institution before IRB application submission. |
| I declare that this research is approved by the institution and is in line with the institution’s standards.  **Declaration on HBRA:**  **☐** I declare that my institution is a Research Institution (RI).  **☐** I declare that should this study be assessed to be a Human Biomedical Research study, my institution will become an RI or find an RI to supervise this study.   |  |  | | --- | --- | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | Signature of CEO or designate | Date |   Name of CEO or designate:  Email of CEO or designate: |

**\*Complete “4. Delegation of Signatory” to appoint a designated signatory**

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| ***(Only if applicable)***  **B4. Delegation of Signatory** |
| I would like to appoint the following personnel to be official signatory responsible for signing on all forms and documents for the purpose of this study.   |  |  | | --- | --- | | **Signing Capacity on behalf of** | **Name & Designation of Appointed Personnel** | | Chief Executive Officer  (or equivalent) |  |  |  |  | | --- | --- | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | Signature of CEO | Date |   Name of CEO: |

# Section C: Research Methodology

The information contained in this section must be self-contained so that it can serve as a succinct and accurate description of the study when it is read by itself. As far as possible, the technical and medical terms should be explained in simple layman language.

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| **C1. Abstract of Proposed Research** | |
| **In no more than 300 words**, please provide an abstract of your proposed research. Describe concisely the following:   1. Specific aims and hypotheses 2. Methodology and approach of the application 3. Importance to proposed research to science, existing knowledge and relevant applications 4. Potential benefits and risks   Please use layman terms. If this is not possible, the technical terms should be explained in simple language. | |
| **C2. Specific Aims and Hypothesis** | |
| State concisely and realistically what the research described in this application is intended to accomplish and/or what hypothesis is to be tested. For qualitative studies, please provide the research question instead. | |
| **C3. Introduction** | |
| **C3.1. Briefly describe the background and the importance of the research. Critically evaluate the existing knowledge and specifically identify the gap that the proposed study is intended to fill.** | |
| Please include the following:   1. General introduction of the study (e.g. Describe current international and/or local standards) 2. Evidence of or any previous literature that suggest current gaps 3. Rationale of study / Why are you prompted to do this study 4. Why this study is important   **\* This writeup should be supported by references/citations to publications.** | |
| **C3.2.** **Please attach at least two relevant peer-reviewed journal articles that support the proposed study methodology.** | |
| Please list at least two relevant papers pertaining to the importance of the study. | |
| **C3.3.** **Please state concisely the importance of the research described in this application by relating the specific aims to the long-term objectives.** | |
| Please describe why this study is important and what possible benefits can be derived from this study. | |
| **C4. Estimated Timeline** | |
| **What are the estimated start and end dates (DD/MM/YYYY) of the research?**  The start date should be after the study has obtained IRB approval. Please note that you should not commence your research prior to IRB approval. | **Start Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_  **End Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **C5. Methodology** | |
| **C5.1. Discuss in detail the experimental design and procedures to be used to accomplish the specific aims of the study. If this study involves a retrospective medical record review, please specify the period of data collection.** | |
| Please provide details on the experimental design used to accomplish the specific aims of the project (e.g. two period crossover, case control, placebo controlled). The description should include, but is not limited to, information on blinding, randomisation, number of study arms, phase of trial, approximate time to complete study recruitment, expected duration of participant participation, sequence and duration of all trial periods (including follow up), changes in scheduling, single or multi centre, healthy or sick population, in or outpatient etc.  If this study involves a retrospective medical records review, please also specify the period of data collection. Please note that for retrospective studies, all the data to be collected should already be in existence and not prospectively collected.  If this study involves the administration of an anonymous survey, please also describe in detail, how the questionnaire/demographic data collection form will be distributed and/or collected anonymously (e.g. the questionnaire/ demographic data collection forms will be given to participants at the clinic and they can return the completed forms by dropping them into a collection box or by using the return envelope provided).  Please note that incidental findings are not test results. Incidental Findings refers to a finding about a research subject that has potential health or reproductive importance to the research subject and is discovered in the course of conducting research but is unrelated to the purposes, objectives or variables of the study. | |
| **C5.2. Please provide details on sample size and power calculation and the means by which data will be analyzed and interpreted (If applicable).** | |
| Details on sample size calculation and the means by which data will be analyzed and interpreted. In particular, specify all of the following:  • Null and alternate hypothesis  • Type I error rate  • Type II error rate  If this is a pilot study and no sample size calculation is performed, please provide a rationale on how the recruitment target is determined. | |
| **C5.3. List all activities that are carried out as part of research in this study. Please state/ list all procedures involved in this research study and attach the data collection form (if any) which will be used for**  **IRB review.** | |
| In this section, please list all activities that are performed solely for the purpose of the research.  E.g. The drawing of an extra 20ml of blood for research, or an additional biopsy taken for research purposes.  NOTES: The data collection form should not contain any participant identifiers (e.g. Name, NRIC, Date of Birth etc.) or allow sticker labels containing participant identifiers to be pasted on it. This is to ensure data confidentiality. | |
| **C5.4. Please describe the participant’s visits (frequency and procedures involved). For studies with multiple visits, please attach study schedule.** | |
| In this section, please list all participants’ visits (frequency and procedures involved). If multiple visits are involved, please attach a study schedule. | |
| **C5.5. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims.** | |
| List the potential difficulties and limitations of the proposed procedures that may lead to failure to achieve the aims and/or failure to complete the study. In addition, list the corresponding alternative approaches to achieve the aims/overcome the difficulties and limitations. | |
| **C5.6. What are the potential risks to participants?** | |
| Please list the potential risks to participants (common as well as the rare ones).  It is not appropriate to provide a nil response as all research procedures have some risks or side effects. For retrospective medical records review or questionnaire study, although the risks are expected to be minimal, there may be a potential risk of a breach of confidentiality. | |
| **C5.7. What are the potential benefits (direct as well as indirect) to participants? Indirect benefit may refer to the medical knowledge gained in the future, from the research.** | |
| Please list the potential benefits to participants (direct as well as the indirect benefits). Indirect benefit may refer to the medical knowledge gained from this research to the participants’ disease. | |

# Section D: Research Participant Characteristics And Recruitment Process

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| **D1. Details of Participants** | | |
| **D1.1. What is the number of participants to be enrolled? Give a breakdown by site of recruitment for multi-centred studies.** | | |
| |  |  |  |  | | --- | --- | --- | --- | | **Institution(s)/ Site of recruitment** | **Target number of research participants** | | | | **Total** | **Male** | **Female** | |  |  |  |  | |  |  |  |  | | | |
| **D1.2. Age Limits** | Lower Age Limit:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Upper Age Limit (if applicable): \_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| **D1.3. Are there any recruitment restrictions based on race of the participant?** | ☐ Yes. Please elaborate: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ☐ No | |
| **D1.4. Are the participants vulnerable or in a dependent relationship with the researchers?**  Please note that research participants who are in a dependent relationship with the researchers should not be approached directly during recruitment, so as to prevent situations where participants consent under duress. | ☐ Yes. Please elaborate: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ☐ No | |
| **D2. Inclusion and Exclusion Criteria** | | |
| Inclusion Criteria | Exclusion Criteria | |
| **D3. Recruitment Process** | | |
| Explain the process of Recruitment in detail; for example, state where and how potential research participants will be recruited/contacted. Please submit a copy of any advertisements/posters that will be used. | | |
| **D4. Financial Reimbursement** | | |
| **Will research participants receive any monetary payments (including transportation allowances) or gifts for their participation in the study?**  If “Yes” is selected, state the anticipated reimbursement amount (per visit and total). | | ☐ Yes ☐ No  Reimbursement amount (if applicable):  Per visit: SGD$\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Total per participant: SGD$\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

# Section E: Data Storage

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| **E1. Research Data Storage** |
| **E1.1. Please state the personal data that will be collected (e.g. names and contact information, etc).** |
| In general, to protect the participant's confidentiality, research data should be coded, and the links between the participant's identifiers and the codes should be stored separately from the research data. |
| **E1.2. Where and how will the research data be stored?** |
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| **E1.3. Who will have access to the research data?** |
| State who will have access to identifiable data and who will have access to de-identifiable data.  There should be limited access to the study data in order to maintain the confidentiality of the research data and participant identities. Please state how will access be controlled and monitored (e.g. research data will be kept in password-protected files or under lock and key, only Study Team Members have access to password/key, password will be changed periodically etc.). |
| **E1.4. What are the measures in place to ensure confidentiality and security of the research data?** |
| ☐ For hardcopy data, they will be stored in designated locked cabinet(s) or room(s) that are accessible to authorized study personnel only.  ☐ For electronic data, they will be stored in a secured computer that is password-protected. The databases used for analysis should not contain participant identifiers. The data linking participant identifiers and the participant identification codes should be stored separately. When portable media (e.g. CD, USB drives etc.) are used to store the data, participant identifiers are stored separately. Only documents used as source documents can contain participant identifiers.  **\* Please provide additional details specific to your study:**  If applicable, indicate how data will be de-identified and who will have access to the identification key.  Some measures may include password protection, security under lock and key, access-controlled office, etc. Common measures employed by investigators to protect confidentiality include storage of records in locked file cabinets, in locked offices, on computers protected by a password, or on computers that are not linked to a network. Another common protection is to code the data with an identifier, and to keep the key to the code located in another physical location or on a separate computer. |
| **E1.5. Describe what will happen to the research data when the study is completed.** |
| Indicate where data will be stored, how long data will be stored for, and how you intend to dispose of the data at the end of the storage period.  Research data should be retained in a secured storage facility for a minimum of 7 years after completion of research study or date of publication of the research using the research data, whichever is later.  These documents should be retained by the Principal Investigator in a secure storage facility. They should be accessible for inspection and copying by authorized authorities.  For clinical trials, according to ICH GCP E6 (R2), the essential documents should be retained until:  i. At least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region; or  ii. At least 2 years have lapse since the formal discontinuation of clinical development of the investigational product; or  iii. These documents should be retained for a longer period if required by the applicable regulatory requirements or by an agreement with the sponsor. |
| **E1.6. Will any part of the study procedures be recorded on audiotape, film/video, or other electronic medium?** |
| ☐ No  ☐ Yes  If yes,   1. **What is the medium (audio tape/ video etc) used for recording?** 2. **Please describe the contents of the recording (e.g. audio-recoding of interview/ focus group discussion, images of facial feature, etc).** 3. **Explain how the recorded information will be used in the study.**   Please explain how the recorded information will be used (e.g. photographs will be taken to assess / compare the disease condition, interviews with the participant will be audio-taped and later transcribed).   1. **For how long and where will the recording medium be stored? Who will have access, how will access be controlled and monitored?**   • Please state location of storage of medium.  • Please state how long the recording medium will be stored.  • If copies are made, who will have access to them, and what are the procedures for accessing and using the data in the recording medium.   1. **How will the recording medium be disposed?**   Please describe how the recording medium will be destroyed. |

# Section F: Participant Information Sheet And Informed Consent Form (PIS-CF)

Please submit a copy of the PIS-CF if waiver is not required.

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| **F1. Describe when the consent process will take place with the potential participant.** |
| Please explain how the participant will be given sufficient time to consider and discuss their participation with family members etc.  Please explain how the participant will be situated in a comfortable place, and have the right frame of mind to consider their participation.  Please explain how the person who would be assigned to take consent would minimize the possibility of coercion or undue influence.  The investigator must take precautions to ensure that in the process of obtaining consent from participants, the time and place of doing so must be suitable and comfortable for the participant to discuss the research with the investigator, and must not be made to feel compelled to participate. The participant must also be given sufficient time to decide whether or not to participate in the research, and have the option of further discussions with their family members before making the decision.  It is also advisable that the attending physician of the participant should not obtain the consent of their own patient for research, as the participant may feel obliged to join the research, or have a heightened sense of faith and trust in their own physician, and may be more likely to participate.  Participants should be approached prior to the initiation of any study procedures and should not be approached in a situation where they may feel compromised (e.g. while in labour, just prior to a surgical procedure or under sedation).  With effect from 1 November 2017, for studies regulated under HBRA, please include a statement that informed consent will be taken in the presence of a witness (applicable to restricted human biomedical research and research that are interventional or invasive).  Informed Consent should be obtained before initiation of the study, i.e. Before any procedures that are being performed solely for the research.  Participants should not be approached when participants are under duress, for example, it would not be appropriate to approach a participant immediately before a procedure or surgery, while in labour, while under sedation and any other situation where a participant might feel compromised.  Participants should be approached in a quiet and conducive environment. It would not be appropriate to approach a participant in an Operating Theatre for a study when he/she is getting ready for a procedure, even though the study is not related to the procedure.  Investigator should also protect the privacy of the participant when approaching the patients to participate in research (e.g. when approaching participants for survey involving sexually transmitted diseases, approaching the participant in the Waiting Area of a General Clinic may violate the participant’s privacy). |
| **F2. Does your study involve potential vulnerable participants whereby obtaining informed consent from the participant is not possible and informed consent is required from a Legal Representative (LR)\*?** |
| ☐ No  ☐ Yes  If yes, please explain:   1. **Why the study requires the informed consent of a LR (e.g. participants are minors, cognitively impaired or unconscious).** 2. **State who LR is (e.g. spouse, parents, guardian etc.).**   \* A LR may give consent on behalf of the individual for participation in a research only when the individual is not capable of giving legally effective informed consent, such as:  a. A child as defined - Persons who have not attained legal age for consent to treatments or procedures involved in the research, which under Singapore law is an individual under the age of 21 years, excluding persons who are below the age of 21 but are married.  b. An individual who is cognitively impaired, or  c. An individual who is unconscious. |
| **F3. Please describe the provisions to protect the "privacy interest" of the participants (e.g. consent will be obtained in a separate room, free from intrusion and participants are comfortable with the proposed settings).** |
| The manner in which the participants are identified and approached for participation in research may constitute an invasion of privacy. The investigator should take precautions to ensure that process of obtaining consent from a research participant preferably conducted in a private consultation room to protect the privacy of the participant. The wishes of the participant must also be respected if they choose not to participate in the research. |
| **F4. Besides the Research Participant Information Sheet and Consent Form, will any other materials or documents be used to explain the study to potential Research Participants (e.g. scripts, handouts, brochures, videos, logs etc.)?** |
| ☐ No  ☐ Yes, please attach the document(s) for review. |
| **F5. Will the study enroll non-Mandarin speaking participants?** |
| ☐ No  ☐ Yes  If yes, |
| **F5.1. What are the possible languages that might be understood by the prospective participant or the legal representative?** |
| ☐ English  ☐ Malay  ☐ Tamil  ☐ Others: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **F5.2. Will the consent be communicated in a language that is understood by the prospective participant or the legal representative?** |
| ☐ No  ☐ Yes, please attach the document(s) for review. |
| **F5.3. How will the Non-Mandarin consent be documented?** |
| Consent Document translated to the language understood by the prospective participant or the legal representative. You may attach the translated consent document, if available. Otherwise, please submit the translated document after the English version has been approved by IRB. Submission of the translated consent forms to IRB should preferably be accompanied by a Certification of Translation from the translator or translation service. |
| **F5.4. Will the study be recruiting participants under emergency situations, when prior consent of the participant is not possible, and the consent of the participant’s legal representative, if present, should be requested?** |
| ☐ Yes, please elaborate.  ☐ No  Emergency Situations  • In emergency situations, when prior consent from the participant him/herself is not possible, the consent of the participant’s legal representative, if present, should be requested.  • When prior consent of the participant is not possible, and the participant’s legal representative is not available, enrolment of the participant should require measures described in the protocol to protect the rights, safety and wellbeing of the participant and to ensure compliance with applicable  The Principal Investigator, who is a specialist, and 1 independent specialist who is not conducting the trial is required to certify in writing that:  - The potential participant is facing a life-threatening situation which necessitated intervention;  - That person is unable to give his consent as a result of his medical condition;  - It is not feasible to request consent from that person or to contact his legal representative within the crucial period in which treatment must be administered;  - Neither that person or his legal representative nor any members of that person’s family has informed the Principal Investigator of his objection to that person being used as a participant in the clinical trial.  • The participant or the participant’s legal representative should be informed about the research as soon as possible and consent to continue should be requested. |
| **F6. Waiver of Informed Consent** |
| ☐ Not applicable  ☐ I require a waiver of:  ☐ Informed Consent as my research involves deception  ☐ Documentation of Informed Consent (i.e. no documented consent) |
| **F6.1. Please justify how your research meets each of the following criteria.** |
| 1. **The research involves no more than minimal risk to the participants.** 2. **The waiver or alteration will not adversely affect the rights and welfare of the participants.** 3. **Whenever appropriate, the participants will be provided with additional pertinent information after participation.** 4. **The research could not practicably be carried out without the waiver or alteration.** |

Section G: Study Administrators

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| **13. Study Administrators**  \* Study Administrators are persons (other than the PI) who are responsible for administrative matters related to the Study. They may be part of the Study Team (Co-Is, collaborators) or outside of the study team. While the PI remains the primary contact person, the ACMS IRB will include the Study Administrators in correspondence for administrative matters related to the Study. Study Administrators may also assist the PI in drafting the various forms and reports, however, only the PI may submit these forms and reports to the ACMS IRB. If there are no Study Administrators, please indicate ‘NA’. |
| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Name** | **Institution** | **Department** | **Designation** | **Office No.** | **Email** | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |

**--------------------------------------END OF FORM-----------------------------------------------**

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| **Checklist of Supporting Documents** | | |
| **Document** | **Attached** | **Not applicable** |
| 1. CVs of PI, Co-I(s), Collaborator(s) (1-page each) | ☐ | ☐ |
| 1. Valid CITI certificate(s) of PI, Co-I(s) | ☐ | ☐ |
| 1. For studies that require consent: Participant Information Sheet and Informed Consent Form (PIS & CF) | ☐ | ☐ |
| 1. If applicable: Questionnaires / Survey Forms / Interview Guides | ☐ | ☐ |
| 1. If applicable: List of variables to be extracted from medical records database | ☐ | ☐ |
| 1. If applicable: Advertisement for recruitment of Participants | ☐ | ☐ |
| 1. For funded studies: Copy of grant award letter | ☐ | ☐ |
| 1. Others (please indicate): | ☐ | ☐ |