The Academy of Chinese Medicine Institutional Review Board (ACMS-IRB) Application Form Workflow

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TABLE OF CONTENTS

1. GENERAL INFORMATION 3

2. APPLICATION FORM SECTIONS 4

2.1 Selection of Application Form 4
2.2 Section A: Protocol Title and Protocol Administrators 7
2.3 Section B: Study Sites, Study Team & Submission Board 8
2.4 Section C: Conflict of Interest 10
2.5 Section D: Nature of Research 11
2.6 Section E: Study Funding Information 13
2.7 Section F: Research Methodology 15
2.8 Section G: Research Details- Clinical Trials 19
2.9 Section H: Recruitment Details 20
2.10 Section I: Study Sites & Recruitment Targets 24
2.11 Section J: Exemption Review Criteria 25
2.12 Section K: Research Participant Characteristics 26
2.13 Section L: Research Participants- Pregnant Women, Foetuses & Neonates 28
2.14 Section M: Research Participants- Children 30
2.15 Section N: Research Participants- Prisoners 32
2.16 Section O: Research Participants- Cognitively Impaired Persons 33
2.17 Section P: Consent Process- Consent Required 35
2.18 Section Q: Consent Process- Waiver Required 40
2.19 Section R: Research Data Confidentiality 42
2.20 Section S: Biological Materials Usage & Storage 44
2.21 Section T: Data & Safety Monitoring 46
2.21.1 Other Attachments 47
2.22 Section U: Declaration of Principal Investigator 47
2.22.1 Endorsements Page 48

Summary of Changes		
Document Version	**Date of Change**	**Summary of Changes**
1.0	TBC	First release

1. GENERAL INFORMATION

a.1. The standard IRB Application Form must be submitted to the ACMS IRB for review. For exemption submission, please submit the IRB Application Form and inform the board that the research proposal is for exemption submission.

a.2. Research involving the following are not considered as Exemption Application:

a. Prisoners
b. Children - when the research involves survey, interview procedures or observations of public behavior, except when the investigator(s) do not participate in the activities being observed;
c. It is an US-FDA-regulated research activity; or
d. Where there is no publicly available information and there is a need to collect identifiers.

b. APPLICATION FORMS

b.1. Use the ACMS IRB Application Form if research activity does not qualify under the Exempt Category. The Form will be reviewed by the Full Board or Expedited route.

b.2. There are criteria for using the ACMS IRB Exemption Application Form.

b.3. The Exemption Criteria do not apply to the following research activity that involves:

a. Prisoners;
b. Children, when the research involves survey or interview procedures or observations of public behavior, except when the Private Investigator(s) (PI) do not participate in the activities being observed; or
c. Is a US FDA-regulated research activity.

b.4. Information not publicly available and if there is a need to collect identifiers, the Study will not qualify for Exemption.

b.5. There are different categories of available for exemption:

(a) Category 1- Research in Normal Educational Practices and Settings

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special TCM education instructional strategies; or (ii) research on the effectiveness of or the comparison among TCM instructional techniques, curricula, or classroom management methods.

(b) Category 2- Anonymous Educational Tests, Surveys, Interviews or Observations

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), surveys interviews (online or paper), or observations of public behaviour (including visual or

auditory recording at a public place), unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or indirectly through identifiers linked to the participants; and

(ii) any disclosure of the human subjects' responses outside of the research could reasonably place participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

(iii) Surveys combined with interventions and/or the collection of bio-specimens and linking to additional individually identifiable data.

(iv) Surveys that contain invasive questions that may cause subjects to experience emotional disturbance or discomfort.

(c) Category 3-Secondary research on existing (or public) datasets or biological materials

Research involving the study of existing data, documents, records, pathological specimens, or diagnostic specimens, if:

- these sources are publicly available* (e.g. data accessible to the general public such as library literature or internet) and if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants;

- For continued use of identifiable data, prior broad consent must have been obtained from the subjects for use in future secondary research.

- No follow-up on contact with the subjects for the secondary research and no return of individual research results (unless required by law)

- No re-identification of subjects once anonymised.
- the reviewed material should be in existence at the time the research is proposed and should not be prospectively collected.

*Medical Records are not publicly available because they are restricted to designated doctors/physicians and healthcare professionals only.

NOTES: Data is considered identifiable if any of the following information is present:

a. Participant Name
b. Address - Street
c. Address - Postal Code
d. Elements of Dates related to a participant in combination with other identifiers. For example, date of birth, admission or discharge dates, date of death
e. Telephone Number
f. Fax Number
g. Electronic Mail Address
h. NRIC Number

i. Medical Record Numbers
j. Health Plan Beneficiary Numbers
k. Account Numbers
l. Certificate/License Numbers
m. Vehicle Identification Number and Serial Numbers Including License Plate
n. Medical Device Identifiers and Serial Numbers
o. Web URLs
p. Internet Protocol (IP) Address
q. Biometric Identifiers (finger and voice prints)
r. Full Face Photographic Images
s. Any Unique Identifying Number, Characteristic or Code Link to Identifier (code)

To qualify for exemption under this category, you cannot collect information that allows you to identify the participants (whose cells/tissues/data are being used in this study) directly or through identifiers linked to the participants unless the information is publicly available.

If the information is not publicly available and you wish to collect identifiers, your study will not qualify for an exemption.

(d) Category 4-Public Benefit or Service Programs

Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) public benefit or service programs;
(ii) procedures for obtaining benefits or services under those programs;
(iii) possible changes in or alternatives to those programs or procedures; or
(iv) possible changes in methods or levels of payment for benefits or services under those programs.

(e) Category 5 – Reporting of Individual Patients' Clinical Results

Writing up or reporting of individual patients' clinical results by the patients' physicians/doctors(i.e. case studies review), provided that the patients' consent for procedures and interventions in clinical management have been obtained and the patients' privacy protected, for example, the review of a TCM treatment programme that includes demographic, clinical and outcome parameters, which are useful in the audit of the programme, or the review of a physician, where the choice of the technique is based on the clinical judgement of the physician and best practices and not on any randomisation procedure.

Researchers who are not the attending physicians in the programme but wish to have access to such information should send their proposals to the IRB in the usual way.

An exemption does not apply when the research activity is supported by funding from Singapore's governmental Departments / Agencies.

(f) Category 6 – Research Using Unidentifiable Data

Research using appropriately designed data escrow or other arrangements in which personal

or other identifying information is securely withheld from researchers by a third-party provider of information, there being no possibility of researchers by themselves being able to trace or reconstruct significant information on the identity of participant donor.

An exemption does not apply when the research activity is supported by funding from Singapore's governmental Departments / Agencies.

(g) Category 8 – Development of Diagnostic Test

The development of diagnostic test kits/apps using existing TCM data.

An exemption does not apply when the research activity is supported by funding from Singapore's governmental Departments / Agencies.

SECTION A: Protocol Title and Protocol Administrators

A.1. Please indicate the Full Protocol Title and Protocol Number (if available) for this Study.

- Protocol Tile
- Protocol Number

A2. You may assign Protocol Administrator for this Study

Protocol Administrators (PA) are persons who are responsible for administrative matters related to the Study. They can be the Study Coordinators, Research Nurses or Clinical Research Associates, and need not be part of the Study Team.

While the Principal Investigator (PI) remains the primary contact person, the ACMS IRB may contact the PA for clarification of administrative matters related to the Study.

Pas may also assist the PI in drafting various online forms and reports. However, only the PI may "submit" these online forms and reports to the ACMS IRB.

This section is optional but PIs are encouraged to nominate at least one PA.

You may select up to 5 PAs.

Name	Institution / Organization	Department	Designation	Office No.	Email

SECTION B: Study Sites, Study Team & Submission Board

B1. Study Sites

a. ACMS and Partner Institution

b. XXX and Partner Institution
c. Other Local Sites and Overseas Sites

B2. Study Team Members

Name	Study Role	Department	Institution	Designation	CV[1]	CITI[2]	SGGCP[3]	Informed Consent Involvement[4]

B3. Submission Board and other IRB

a. Has the Study been submitted to another IRB?

- No
- Yes – indicate which IRB

b. Has the application been previously rejected by any IRB? (Including ACMS IRB)

- No
- Yes – indicate which IRB and provide reasons for the rejection

SECTION C: CONFLICT OF INTEREST (COI)

C1. Does the PI or any Study Team Member have any potential conflict of Interest? This declaration is also for the immediate family members of the PI and Study Team Members as follows:

a. All Study Team Members must submit their Declarations together with the Application.

b. Conflicting Interest – A conflicting interest can be broadly defined to refer to any interest of the investigator or immediate family (includes spouse, children, parents and siblings that competes with the investigator's obligation to protect the rights and

[1] The CV information will be used to assess the qualifications of the PI and Study Team Members.

[2] Study Team Members who are from ACMS & Partner Institutions must submit their CITI completion report. Study Team Members who are not from SingHealth & Partner Institutions are encouraged to complete the CITI online course and attach the CITI completion report. However, if you wish to request for waiver of this requirement, please complete the Waiver of CITI Certification Form and attach a copy of the completed Form and send as part of the application.

[3] SGGCP certificate is required for all Site-Principal Investigators conducting clinical trials.

[4] Only Study Team Members or research assistants who have been delegated by the PI can obtain consent from the participants. This should be documented in the Study Responsibility Log. It is the responsibility of the PI to ensure that the Study Team Members who are delegated to obtain consent have received proper training (e.g. CITI, SGGCP)
The delegated Study Team Member should also be appropriately qualified to adequately answer questions from potential participants. For clinical trials here a medical opinion is required, a medically trained Study Team Member should conduct the informed consent so that the participant can have his/her questions adequately answered.

- Only Study Team Members who have been properly trained (e.g. CITI, SGGCP) to obtain consent and designated with the responsibility of taking informed consent from research participants can obtain consent.
- Informed consent discussion should be conducted by the PI, Co-PI or a member of the Study Team Members who is listed in the ACMS IRB Application Form as the designated person for conducting the Informed Consent discussion, must be presented in a language that can be understood to the participant.
- The Study Responsibility Log must be updated with the names of the Study Team Members who are assigned to take informed consent.

welfare of research participants.

c. Financial Interest – 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.

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

e. It is the responsibility of the PI to check and ensure accuracy of the information provided.

Name	Study Role	Department	Institution	Yes / No	
				o Yes	o No

f. The COI Declaration Form should submitted through the study amendments should any of the circumstances relevant described herein changed during the conduct of the research.

- Please complete all the boxes in the Declaration Form, details of the all the COI, and describe a plan to manage all of the COI.

□ Financial interests (e.g. stock, stock options or other ownership interests) in the assets of liability of any organization that may benefit from the research activity.

□ Payments (e.g. salary, consultation fees, speaking fees, or honoraria) from any organization that may benefit from research activity

□ Intellectual property rights or proprietary interests (e.g. patents, copyrights and royalties from such rights) related to the research.

□ Options or other compensation arrangements that could be affected by the outcome of the research.

□ The Sponsor Company supporting this study offers incentives connected with participant recruitment or completion of research study (e.g. finder's fee, recruitment bonuses…) that will be paid to the research staff.

□ Others - specify (financial / non-financial conflict)

Please provide details to all the above COI indicated "Yes"

g. Please describe the plan to manage all of the above COI. You may include the mechanism and processes in place to manage the COI (e.g. resignation of position, independent data analysis, data safety monitoring, blinded study, ad hoc review committee). You may also include the COI will be disclosed to the participants (e.g. through the written informed consent Form, oral presentation… (if any of the above is indicated "Yes"

h. The plan may include the mechanism and processes in place to manage the COI (e.g. resignation of position, independent data analysis, data safety monitoring, blinded study, ad hoc review committee) including if the COI will be disclosed to the participants (e.g. through the written informed Consent Form, oral presentation etc..)

SECTION D: NATURE OF RESEARCH

D1. Select one category that best describes your research activities.

a. Clinical Trials (includes Drug, Device and Procedure Trials)

This research involves administering a drug, device, or biologic as part of the research intervention, or performing surgical procedures as part of the research intervention.

- Indicate what the research study involves
  - Drug / Biologic
  - Device
  - Surgical / Radiotherapy Procedure
- For Drug / Biologic, indicate Phase of the trial e.g. Phase I, Phase IIa etc.
- If a Clinical Trial Certificate, Clinical Trial Authorisation or Clinical Trial Notification is required, the PI must be a locally registered doctor (at least an Associate Consultant grade and above or dentist must be the PI.
- If the registration condition requires the doctor to "work under supervision", a statement from the doctor's supervisor indicating support for the doctor's involvement as the PI of the study.

  - What does the study involve?
    - Drug / Biologic (indicate Phase of the trial)
  - Device
  - Surgical / Radiotherapy Procedure

b. Questionnaire / Survey / Interview:

This includes administering questionnaires / surveys / interviews and may include a medical records review component.

If a combination of medical record review and questionnaires / survey / interviews are involved, select "Questionnaire / Survey / Interview.

c. Medical Records Review

This involves collection of data for a specific research project by reviewing of patient medical records including results of routine diagnostic tests performed for standard

clinical purposes.

The accessed data could be prospectively and / or retrospectively collected.

d. Clinical Research

Choose this if your research involves:

- Collection of blood by venipuncture, finger prick etc. or
- Prospective collection of biological specimen by invasive or non-invasive means including biopsies, Fine needle aspiration cytology (FNAC), fundoscopy etc. or
- Collection of data through research procedures such as Xrays, MRIS, ultrasound, ECG, EEG, etc. or
- Any other research categories outside those listed above.

Submission to HSA might be required if you are conducting clinical trials. If in doubt, you should check with HAS.

Is this a US FDA IND / IDE study or data is intended to be reported to FDA in support of an IND / IDE Application?

- No
- If yes, indicate the study type □ IND
  □ IDE

SECTION E: STUDY FUNDING INFORMATION

E1. Please give information regarding study's Funding Source and Sponsor Information:

a. No funding is required for this study to be carried out or use of Department Fund

b. Pharmaceutical / Industry Sponsored:

- An initial ACMS IRB Application review fee of S$1070 (including 7% GST) is payable for studies which are initiated by industry or commercial entities.
- The cheque should be made payable to "Academy Chinese Medicine Singapore".
- When sending the cheque, please quote the ACMS IRB Reference Number, full protocol title, PI's name, department and institution and Sponsor's contact person (name and mailing address).
- ACMS IRB will not release the Approval Letter if payment has not been received. For more payment options, please contact the ACMS IRB Secretariat.
- Required information:
  - Name of Sponsor Company and contact person
  - Name of Clinical Research Organization (CRO) if applicable

- CRO's contact details
- Payment of IRB review fees – Information for invoice: Company registered name, Company registration number, Company registered address and mail address if different from registered address, name and designation of person for whom we direct the invoice to, and contact number.

c. Is the sponsor offering any incentive connected with participant recruitment or completion of research study e.g. finder's fee, recruitment bonuses etc) that will be paid to the research staff?

d. For Grant supported submissions, please provide the following information:

- Name of Grant Agency and Grant Name
- Deadline of Grant application (if applicable)
- Is the Study dependent on grant approval? If no, indicate alternate source of funding
- If Grant approved, attach the Grant Approval Letter.
- For Grant option, the ACMS IRB may only start reviewing the study when preliminary results for the Grant Application is available. Please contact the ACMS IRB once you have received information on the grant results to start the IRB review process. If your Grant Application was not successful, please advise the ACMS IRB on your next course of action (e.g. withdrawal of the study, look for alternative funding …)

E2. Payment of ACMS IRB review fees – Cheque / Telegraphic Transfer Number and name of Bank.

Information for invoice:

- Company registered name
- Company registration number
- Company registered address
- Company mailing address
- Company mailing address if different from registered address
- Name and designated of the person to whom we direct the Invoice to
- Contact number

E3. Who will be responsible for the payment and compensation injury or illness to participants arising from participation in the study?

E4. Who will be responsible for research-related costs? For sponsored studies, please list the costs that will be borne by the sponsor[5]

[5] It is generally not appropriate for research participants to pay for research-related procedures. The PI should ensure that funding is available to cover these costs (e.g sponsor by Pharmaceutical Company, Grant etc).
For Sponsored studies, please attach or include a payment schedule
For PI initiated studies, please include the payment / reimbursement information which will be reflected in the Informed Consent

SECTION F: RESEARCH METHODOLOGY

The information contained in this section should provide a succinct and accurate description of the study. As far as possible, the technical and medical terms should be explained in simple layperson language.

For ACMS EXEMPTION APPLICATION, only F1, F2 and F8 – F16 applies.

F1. Please provide an abstract of the proposed research to include the following information up to 300 words:
- Aims
- Methodology
- Importance of proposed research to science or medicine
- Potential benefits and risks

F2. What are the specific aims and hypothesis of this study?
- Describe concisely the specific aims and hypothesis of this study.

F3. Please briefly describe the background to the current study proposal.
a. General introduction of the study (e.g. Describe current international and / or local standards)
b. Critically evaluate the existing knowledge and specifically identity the gap that the proposed study intends to address.
c. Evidence of any previous literature that suggest current gaps.
d. Rationale of study / Why are you prompted to do this study?

F4. Please provide a list of relevant references.
- List at least two relevant papers / publications relating to the importance of the study.

F5. Please attach at least 2 relevant publications that support the conduct of the study.

File Name	Description	Version Number	Version Date

F6. Please provide an account of the PI's preliminary studies and progress reports (if any) pertinent to this application.
- If the PI or study team has done related studies for the current submission, include the relevant information (e.g. a short description of the previous study / studies to support this study).

F7. 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.

F8. 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.

a. Provide details on the experimental design to accomplish the specific aims of the study (e.g. two period crossover, case control, placebo controlled).

b. The description should include, but is not limited to, information on blinding, randomization, number of study arms, phase of trial, approximate time to complete study recruitment, expected duration of participant participation, sequence and duration of all trials periods (including follow up), changes in scheduling, single or multi-center, healthy or sick population, in or outpatient etc.

c. If the study involves a retrospective medical records review, specify the period of data collection. For retrospective studies, all the data to be used should already been in existence and not prospectively collected.

d. If it is administration of **anonymous survey**, describe in details, how the questionnaire / demographic data collection forms will be distributed anonymously (e.g. the forms will be given to the participants at the clinic and completed forms returned by using the "returned' envelope or through a collection box.

F9. Please provide details on sample size and power calculation and the means by which data will be analyzed and interpreted (if applicable).

a. 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

b. If this is a pilot study and no sample size calculation is performed, please provide a rationale on how the recruitment target is determined.

F10. 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 ACMS IRB review.

a. List all activities that are performed solely for the purpose of the research.
   - The drawing of extra 20 ml of blood for research, or an additional biopsy taken for research purposes.
- The data collection Form should not contain any participant identifiers (Name, NRIC, DOB …) or allow patient labels containing participant identifiers to be pasted on it.

This is to ensure data confidentiality.

Data Collection Form

File Name	Description	Version Number	Version Date

F11. Please describe the participant's visit (frequency and procedures involved). For studies with multiple visits, please attach study schedule.

- List all participants' visit (frequency and procedures involved). If there are multiple visits, attach the study schedule.

Visit Schedule

File Name	Description	Version Number	Version Date

F12. 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.

F13. What are the potential risks to participants?

- List the potential benefits to participants (common as well as rare ones)

F14. What are the potential benefits to participant's (direct as well as indirect) to participants/ Indirect benefit may refer to the medical knowledge gained in the future from the research.

- List the potential benefits to participants (direct as well as indirect benefits). Indirect benefit may refer to the medical knowledge gained from this research to the participants' disease.

F15. What is the estimated timeline for this study?

- Estimated start date – the date should be after the study has obtained the ethics approval. In a retrospective medical records review study, this is the period when you will conduct the study, not the period for which case notes will be retrieved and reviewed.
- Estimated end date

F16. Does this study have a Study Protocol?

- No
- Yes - Please attached a copy of the Study Protocol.
- Investigators conducting Clinical Trials must submit a Study Protocol for ACMS IRB review.

Study Protocol

File Name	Description	Version Number	Version Date

F17. The PI is responsible for ensuring that all study participants give informed consent before enrolling into the study.

a. ACMS IRB requires that written informed consent should be obtained from all participants and documented prior to their participation in any research, unless the ACMS IRB approves the waiver of consent or waiver of documentation of consent.

b. If "A combination of both Informed Consent and Waiver of Consent is required for different Study populations, please elaborate:
- why a combination of both informed consent and waiver of consent is required,
- which population(s) will require waiver of consent, and
- which population(s) will be able to give consent

c. Consent Forms for different applicable scenarios:
- Informed Consent will be taken for all study participants
- Waiver of Informed Consent is requested for all study participants
- A combination of both Informed Consent and Waiver of Consent is required for different study populations

SECTION G: RESEARCH DETAILS – Clinical Trials

This section applies only to ACMS IRB Application and for Clinical Trials.

G1. Describe the study protocol(s) to be used. Include information of the study – drug / device / surgical procedures that will be used in the trial. If the study involves the use of study drug / device, describe how you plan to manage the receipt, handling, storage, utilization, and disposal of the study drug / device.

Examples include, but are not limited to:
- Background information on the trial product, safety issues and duration of exposure.
- For drugs, include
  - Information on dosage. Clearly explain the rationale for the dose used during the study.
  - Describe in what form the study drug will be dispensed to the participants.
  - Describe the drug regimen to be used.
  - State any special precautions or warnings relevant for the study drug administration.
  - If applicable, describe if there will be blinding, the measures that will be undertaken to blind the study participants and / or study staff from participant treatment assignments.
  - State when un-blinding is expected and if / when participants will be told their assignments.
  - Describe product's storage needs. Include storage requirements and stability (temperature, humidity, security and container).

G2. Attach the Investigator's Brochure or local product information sheet / leaflet, as applicable
Brochure / local product information

File Name	Description	Version Number	Version Date

G3. Describe the standard / alternative treatments used at your institution for this condition.

- If the drug / device / procedure is the experimental aspect of the study, please indicate the standard / alternative treatment available for the condition of the participant.
- Indicate "NA" if this section does not apply to your study.

G4. Is this a placebo controlled trial?

- No
- If "Yes",
  - Explain what 'standard of care' therapy is available for this condition.
  - Discuss the ethical implications of using placebo instead of 'standard of care' therapy in this situation.
  - Address the issues of safety and efficacy of other available therapies.
  - What is the total duration the study participant would be on the placebo arm of the study?
  - What is the greatest potential harm that the study participant might be exposed to as a result of not receiving effective therapy?
  - What are the procedures in place to safeguard study participant receiving placebo?
  - Do you have any other comments supporting the use of a placebo in your study?

SECTION H: IRBRUITMENT DETAILS

This section applies only to ACMS IRB Application.

H1. How will potential participants be identified? Please √ all the applicable boxes.

a. Categories of recruitment

□ Referral by attending healthcare professional

□ Patients of study team - Do the potential research participants have a dependent relationship with the study team (doctor-patient, employer-employee, supervisor-subordinate, teacher-student, departmental staff relationships)?

□ Databases

□ Other methods of participant identification (healthy volunteers – describe how they are identified.

H2. Who will make the first contact with participant?

a. Please identify the person who will make the first contact with participants.
b. All patients should be approached (first informed about the study / trial) by their own treating physicians to participate in the project when they come for their regular clinic visits or when they are admitted to the hospital.
c. The treating physicians should see the patients' consent to be referred to the study team.
d. Consent may be obtained by the Investigators of this study who may not be the treating physicians of the patients.

H3. How will the participant be contacted?

a. Please indicate if potential participants will be recruited by a face-o-face contact when they come for their prospective regular clinic visits.
b. If you intend to call back patients who have visited the hospital / clinic in the past, please note that you must obtain permission from the primary physician / head of department before calling these patients (if you are not the attending physician or these patients).
c. An invitation letter should be mailed to the potential participants before calling them
   - The letter should have the title of the study, purpose and procedures involved, risks and benefits, and the person to contact for more information.
d. Please submit a copy of the Invitation Letter and a sample telephone script (Section H4 below) for ACMS IRB review.

H4. Will any advertising / recruitment strategies be used (e.g. talks in public place, societies ...)

a. Any advertisement to recruit participants should be limited to the information the prospective participants need to determine their eligibility and interest.
b. Guidelines for preparing advertisements and information to be included:
   - Volunteers are being recruited for research
   - Name and address of the PI
   - Purpose of the research
   - Summary of the eligibility criteria of research participants
   - A straightforward description of potential benefits to participant
   - A brief list of procedures involved.
   - Time or other commitment required of the participant.
   - Any compensation or reimbursement (advertisement may state this but there should be no bold or enlarged print or other means of emphasizing payment.
   - The amount to be paid should not be known
   - Location where the research will be conducted
   - Contact person and details for further information

c. The advertisement should not – explicitly or implicitly:
   - State or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and protocol
   - Claims of safety, effectiveness, equivalence or superiority in reference to the drug, device or procedure under investigation
   - Use of the term "new" in reference to a treatment, drug or device without explaining that the test article is investigational
   - Use the term "free" in reference to a treatment or procedure
   - Use of catchy words like "exciting", "fast" or "earn"

- A statement of implication of Ethics Committee / IRBs / Ministry of Health / Health Sciences Authority endorsement of the research
- Use of exculpatory language
- Make claims about the drug, biologic or device under investigation that are inconsistent with currently approved labelling

d. For posters – state the locations where the posters will be placed (hospital staff lifts, clinic general waiting areas…)

Poster

File Name	Description	Version Number	Version Date

e. For brochures – state the locations where the brochures will be placed (clinic general waiting areas)

Brochures

File Name	Description	Version Number	Version Date

f. Advertisements in Newspaper / Magazines / Publications - state which publisher will be carrying the advertisement, the frequency of the advertisement.

Advertisements

File Name	Description	Version Number	Version Date

g. Advertisements on Radio / TV – state which TV station will carry the advertisements, frequency of the advertisement.

Advertisements on Radio / TV

File Name	Description	Version Number	Version Date

h. Letter of invitation to potential research participants[6]

Invitation Letter

i. Letter to Doctors requesting referrals[7]

Letter to Doctors

File Name	Description	Version Number	Version Date

j. Other types of materials will be used – elaborate and attach a copy for ACMS IRB review

Other materials

File Name	Description	Version Number	Version Date

H5. Will any advertising / recruitment strategies be used – attach a copy for ACMS IRB review.

[6] Letter of invitation – email, letters or any form of documents used as part of the recruitment strategy, with the intention of inviting the research participants to participate in the study.

[7] IRB review and approval is not required for letter to doctors for referring potential participants

- Talks in public places, public forums at hospitals and or general public areas such as Community Centers, professional societies …

H6. What is the recruitment period (if applicable) – provide an approximate recruitment period.

- Start date
- End date
- For medical records review, indicate the period the data that will be extracted for review

H7. How long will the participants be directly involved in the study (if applicable)? This includes the time from the screening procedures till completion of follow-up tests or examinations.

- Indicate the time period (e.g. number of weeks) during which the participants will be involved in the study related procedures or taking study medication.
- Indicate "NA" if these is no participant interaction in this study.

SECTION I: STUDY SITES & IRBRUITMENT TARGETS

I1. Please state the target number of research participants to be recruited for each study site in Singapore. If the exact numbers are not available, please give an approximate number range in the recruitment target.

a. When determining the estimated number, please make provisions for participant withdrawals.
b. The total number of participants enrolled does not only refer to the participants who are still in the study.
c. Participants who have withdrawn also count towards the total number of participant recruited in the study (participants who have withdrawn also count towards the total number of participant recruited into the study.
d. The estimated number of males, females and children for IRB to have an overview of whether there is any recruitment restrictions based on the gender of the research participants and whether children need to be included because they will need special protection.
e. A study amendment must be submitted and approved by the IRB if additional participants over the estimated maximum number are required. Otherwise it is considered a non-compliance.
f. The study site(s) reflected in this section are based on the sites indicated in Section B1. If you would like to add additional site(s), add them under Section B above.

Participant recruitment

No	Study Site	Total recruitment Target	Adults (Male)	Adults (Female)	Children

I2. Is this part of an International Study?

a. No
b. If "Yes", state the total number of worldwide research participants targeted for

enrolment into this study. If exact numbers are not available, please give an approximate number

SECTION J: EXEMPTION REVIEW CRITERIA

This section only applies to ACMS IRB Exemption Application.

J1. Please describe and state the source of your samples / data.

- Describe where and how you obtain the samples / data.
- To qualify for Category 2 and / or 4, the source of the samples / data must fulfil one of the following criteria:
  - Information must be recorded by the Investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participant (i.e. the existence of a one-way identifier, such as a code that can be used to identify a participant, disqualifies the research as Exempt) or
  - Sources are publicly available (accessible to general public such as library literature or designated doctors and healthcare professionals only.

J2. Criteria to qualify for Exemption from ACMS IRB review.

a. The research involves no more than minimal risks to the study participants:
   - If "No" is indicated, your study does not qualify for Exempt review.
   - If "yes, provide further information on (a) above.

b. The selection of participant is equitable:
   - If "Yes", no further response in question in J2 are required.
   - If "No" please provide a reason why the selection of study participants is not equitable (e.g. the disease only affect the X population).

c. recording of identifiable information
   - No recording of identifiable information
   - Identifiable information is recorded and there are adequate provisions to maintain the confidentiality of the data.
   - **If you have indicated Exempt categories 2, 4 or 8, identifiable information cannot be** rec**orded – amendment to the ACMS Application Form is required.**

d. Privacy interests of the study participants
   - It is not applicable as there are no interactions with study participants.
   - There are interactions with study participants and there are adequate provisions to maintain the privacy interests of the study participants.

e. Informed consent
   - Informed consent will be taken for all study participants.
   - Waiver of Consent is requested for all study participants.
   - A combination of both Informed Consent and Waiver of Consent is required for different study populations.
     - Please elaborate why a combination of both Informed Consent and Waiver of Informed Consent is required, and which population(s) will required waiver of consent and which population(s) will be able to give informed conse

SECTION K: RESEARCH PARTICIPANT CHARACTERISTICS

K.1 List the inclusion criteria for research participants in this study.

a. State the inclusion criteria (set of conditions that must be met in order to participate in the study) for research participants relevant to this study (e.g. age, gender, blood sugar level, blood pressure, type and stage of disease…)
b. For global studies, please modify the criteria according to local regulations (e.g. persons below the age of 21 and are unmarried are considered minors in Singapore and would require parental consent prior to participation).

K2. List the exclusion criteria for research participants in this study.

a. State the exclusion criteria (set of conditions participants must not have) for research participants relevant to this study (e.g. age, gender, blood sugar levels, blood pressure, type and stage of disease…)
b. For global studies, please modify the criteria according to local regulations (e.g. persons below the age of 21 and are unmarried are considered minors in Singapore and would require parental consent prior to participation).

K3. Please state the age group of the research participants.

- Lower age limit
- Upper age limit
- Persons under the age of 21 are considered minors in Singapore and will require parental consent prior to participation

K4. Are there any recruitment restrictions based in the gender of the research participants (e.g. only males will be included in this study)?

- No
- Yes - elaborate

K5. Are there any recruitment restrictions based in the gender of the research participants (e.g. only Chinese participants will be included in this study)?

- No
- Yes – elaborate

K6. Do the potential research participants have a dependent relationship with the study team (e.g. doctor-patient, employee-employer, head-subordinate, student-teacher, departmental staff relationship)?

- No
- Yes
  - State clearly the dependent relationship of Study Team Members with the research participants (e.g. Study Team Members are the primary physicians to the research participants).
  - Describe how the Study Team will manage the dependent relationship to prevent coercion or undue influence (e.g. informed consent will not be taken by the primary physicians, but explained by another Study Team Member who

is not the primary physician of the participant).[8]

K.7 Does the study involve any vulnerable research participants?

a. No
b. If "Yes", √ the applicable population(s):
   - □ Pregnant Women, Fetuses, Neonates (please answer Section L)
   - □ Children (persons who are less than 21 years of age and are unmarried), please answer Section M).
   - □ Prisoners (Please answer Section N).
   - □ Cognitive impaired Persons (please answer Section O).
   - □ Others - elaborate
     - o Why does your research need to involve this group of vulnerable participants? - elaborate
     - o What are the additional safeguards that will be provided to protect the rights and welfare of this group of vulnerable participants? - elaborate

K8. Does the study involve any of the following?

- □ Inpatients
- □ Outpatients
- □ Healthy Volunteers
- □ Not applicable

SECTION L: RESEARCH PARTICIPANTS – PREGNANT WOMEN, FETUSES & NEONATES

This section applies only to ACMS IRB Application that considers "Pregnant Women", Fetuses & Neonates as indicated in K7

For research studies that involve pregnant women, fetuses & neonates, the research must meet specific criteria. Please provide protocol specific information explaining how your proposed research project meets them.

L1. Indicate if your research involves:

- □ Pregnant Women and Fetuses
- □ Neonates of Uncertain Viability and / or Non-viable neonates
- □ Non-viable neonates

Please ensure that your research does not involve maintaining the vital information of the neonate artificially or terminating the heartbeat or respiration of the neonate.

[8] Ethical concern – given the dependent relationship, the participant may feel obliged to participate in the research, e.g. out of fear that declining to participate in the study will result in resentment or abandonment by the primary physician.

L2. Describe if appropriate preclinical studies, including studies on pregnant animals and clinical studies including studies on non-pregnant women, have been conducted and data is available to assess risks to pregnant women and fetus.

L3. Describe if the risk to the fetus is the least possible in order to achieve the research objectives.

- Explain how you would minimize the risk to the fetus to attain the research objectives.

L4. Describe the additional safeguards that will be provided to protect the rights, safety and welfare of these vulnerable participants.

- Kindly state all additional steps that will be taken to minimize coercion and to protect the rights, safety and wellbeing of study participants.

L5. Special Informed Consent Requirements (Check that all apply)

□ I will obtain consent from the pregnant women because:
  □ Research holds out the prospect of direct benefits to the pregnant women.
  □ Research holds out the prospect of direct benefits to both the pregnant women and the fetus.
  □ Risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.

□ I will also obtain consent from the father because the research holds out the prospect of direct benefit solely to the fetus.

□ The Informed Consent document(s) will provide information regarding the reasonably foreseeable impact of the research on the fetus or neonates.

L6. Assurance by PI

- There will be no inducements, monetary or otherwise, offered to terminate a pregnancy.
- Individuals engaged in the research will not have any part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.
- Individuals engaged in the research will not have any part in determining the viability of a neonate

I agree with the above statements. □ Yes □ No

SECTION M: RESEARCH PARTICPANTS – CHILDREN

This section applies only when Children is selected in K7 of the ACMS IRB Application.

M1. Describe if appropriate studies have been conducted on animals and adults first, and data is available to assess risks to children participating in the research.

- If the above studies have been conducted and published, please provide a copy of the paper

M2. Please justify the need to involve children. Can the research question be answered through alternative means (e.g. involving adults only)?

a. Explain why the research has to be conducted in children e.g. research question is related to disease or treatment in children.

b. Research involving children will be classified into one of the following 3 categories:

- Category 1 – Research that does not involve more than minimal risk.
- Category 2 – Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual participant and the relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by alternative approaches.
- Category 3 – Research involving greater than minimal risk and no prospect of benefit to the individual participant. In order to approve the research in this category, the ACMS IRB must determine that:
  - The risk of the research presents no more than a minor increase over minimal risk.
  - The intervention or procedure presents experiences to the participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations.
  - The intervention or procedure is likely to yield generalizable knowledge about the participant's disorder or condition which is of vital importance for the understanding or the amelioration of the disorder or condition.

M3. Describe how the relation of potential benefits to risks is at least as favorable as that presented by alternative approaches.

a. Justify the potential benefits of participation are comparable to the risks of standard treatment or other alternatives (e.g. use of medication other than study drugs or undergoing procedures other than those listed in the study).

M4. Describe any additional safeguards that will be provided to protect the rights, safety and welfare of these vulnerable participants.

b. State if steps will be taken to minimize risks and to protect rights, safety and welfare of these vulnerable participants.

M5. What are the provisions for obtaining the child's assent and parental permission?

a. PARENTAL PERMISSION – ACMS IRB will use the following guidelines to determine parental permission / consent requirements:
- If both parents are available and willing to provide permission, the PI should obtain consent from both parents.
- For research approved under Category 1 and 2 (See Section M2), permission

from at least one parent or legal guardian must be obtained.

- For research approved under Category 3 (See Section M2), permission must be obtained from both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

b. ASSENT BY THE CHILD

- In general, the ACMS IRB recommends that assent be obtained from children who are over 6 years old.
- Primary school aged children (6-12 years old) should be provided with a short assent document that clearly explains discomforts and inconveniences that the child may experience if he or she agrees to participate.[9]
- The document should also emphasize the voluntary nature of the research and that the child may refuse to participate without any consequences.
- For research involving children of Secondary School age and older children (13-20 years old), provision may be made in the same consent document that will be signed by the parents for the signature of the child.[10]
- The ACMS IRB must review and approve the assent document and the consent document prior to initiation of the study.
- Please √ all sections that are applicable for this study.
  - Assent will be obtained from all children above 6 years old and Parental Permission will be obtained.
    - □ Provide a separate Assent Form to document assent for children aged 6-12 years old (attach the signed Assent Form)
    - □ Provide provision for Signature of Child or Parental Consent Form for children aged 13-20 years old.

Signature of child or Parental Consent

File Name	Description	Version Number	Version Date

  - Assent will not be obtained from children. Only Parental Permission will be obtained.
  - Parental Permission will not be obtained from the parents. Only assent will be obtained (Attach Assent Form)

Assent Form

File Name	Description	Version Number	Version Date

  - Neither the child's Assent nor Parental Permission will be obtained.

SECTION N: RESEARCH PARTICPANTS – PRISONERS

This section applies only to ACMS IRB Application.

Please provide protocol specific information explaining how your proposed research project meets the

[9] For studies recruiting participants aged 6-12 years old, the participants should be provided an Assent Form to document their agreement regarding participation. The Assent Form should be written using simple words which an average 6-12 years old is able to understand.

[10] For studies recruiting participants aged 13-20 years old, the participants' Assent Form should be sought and documented using the full Informed Consent Form, together with the documented Informed Consent of the parent or the legal representative.

following criteria.

N1. How does the research purpose justify enrolling prisoners?

- Justify the reason for including prisoners in this study (e.g. particular research question can only be addressed by involving prisoners).

N2. Is there any evidence of duress, coercion, or undue influence in the particular prison(s) from which participants will be recruited?

- State if there will be any duress, coercion, or undue influence in the particular prison(s) from which participants will be recruited and provide the justification.

N3. Are potential research related risks to prisoners comparable to risks that would be accepted by non-prisoner volunteers?

- Justify if he risks of participating in a study to prisoners will be acceptable by non-prisoner research volunteers.

N4. Describe the systems in place to ensure participant and data confidentiality.

- Explain all steps which will be taken to ensure the privacy of research participants and confidentiality of data e.g. where and how consent will be taken, where the data will be stored, if the data is coded, who will have access to the data etc.

N5. Describe any additional safeguards that will be provided to protect the rights, safety and welfare of these vulnerable participants?

- Indicate if any additional steps are taken to ensure the rights, safety and wellbeing of research participants.

SECTION O: RESEARCH PARTICPANTS – COGNITIVELY IMPAIRED PERSONS

This section applies only to ACMS IRB Application.

Q1. Is this research relevant to this group of participants who are cognitively impaired?

- If "Yes", state and justify the reason for including cognitively-impaired persons in this study (e.g. particular research question can only addressed in cognitively-impaired persons).
- If "No", it is recommended that the study be conducted in mentally competent participants instead.

Q2. Are adequate procedures for evaluating the mental status of prospective participants employed to determine if they are capable of providing consent?

- If "Yes", provide details on the procedures for evaluating the mental status of prospective participants (e.g. with validated assessment such as Mini-mental State Examination (MMSE)).

- If "No", justify the reason for not evaluating the mental status of prospective participants.

Q3. Will legal representatives (LRs) be approached to give consent on behalf of the individuals judged incapable of providing consent?

- If "No", elaborate why a legal representative could not be approached to give consent on behalf of the individuals judged incapable of giving consent.

Q4. Will a separate Consent Form be used for cognitively impaired persons?

- If "Yes", attach a copy of the Separate Assent Form. This should be a separate Assent Form written in simple words for cognitively impaired persons to understand. Attach the Assent Form.

Assent Form

File Name	Description	Version Number	Version Date

- If "No", justify the reasons for not obtaining assent from the participants.

Q5. If a participant is incapable of giving valid consent, will his / her objection to participant be overridden?

- Yes
- No

Q6. Will an advocate or consent monitor be appointed to ensure that the preferences of potential participants are elicited and respected?

- Yes
- If "No", justify the reason for not appointing an advocate or consent monitor approached to give consent on behalf of the individuals judged incapable of providing consent.
- A patient advocate or an advocacy group can provide an understanding of the participant population and how the research is likely to impact them.
- Advocates or consent monitors are appointed to monitor the consent process, to access the participant's level of impairment, and to determine whether the participant is capable of providing, and has in fact provided the requisite consent or assent.

Q7. Will an advocate or consent monitor be appointed to ensure the continuing agreement of participants to participate as the research progresses?

- Yes
- If "No", justify the reason for not appointing an advocate or consent monitor to ensure the continuing agreement of participants to participate as the research progresses (e.g. the research study only involves a single visit).
- A patient advocate or an advocacy group can provide an understanding of the participant population and how the research is likely to impact them.
- Advocates or consent monitors are appointed to monitor the consent process, to assess the participant's level of impairment, and to determine whether the participant is capable of providing, and has in fact provided the requisite consent or assent.

Q8. Will the patient's physician or other healthcare provider be consulted before any individual is invited to participate in the research?

- Yes
- If "No", justify the reason for not consulting the patient's physician or other healthcare provider (e.g. the participation in the research study does not interfere with his/her routine clinical care).

Q9. Is there a possibility that the request to participate itself, may provoke anxiety, stress or any other serious negative response?

- If "yes", provide details on the additional measures that will be taken to manage this (e.g. a psychiatrist will be present during the consent taking process to monitor the signs and symptoms displayed by the potential participants, and the consent taking process will be stopped if potential participants show any signs of distress).
- No

Q10. Are there any other additional safeguards in place to protect the rights, safety and wellbeing of these vulnerable participants?

- Yes - elaborate
- No

SECTION P: CONSENT PROCESS – CONSENT REQUIRED

This section applies only when "Informed Consent" or "A Combination of both Informed Consent and Waiver of Consent" is required (F17 ACMS IRB Application Form or J2 ACMS IRB Exemption Application Form).

P1. The PI is responsible for ensuring that all Study Participants give informed consent before enrolling into the study.

- 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 or under duress (e.g. while in labor, prior to a surgical procedure or under sedation).
  - 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 e.g., it would not be appropriate to approach a participant immediately before a procedure or surgery, while in labor, while under sedation and any other situation where a participant might feel compromised.

P2. Where will the consent process take place with the potential participant (e.g. inpatient room ward, outpatient clinic…) Justify why the place chosen for the consent process is suitable?

- 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 a General Clinic Waiting area may violate the participant's privacy.

P3. Please describe the consent process:

a. Explain, if the time which you plan for the consent process to take place would give the participant sufficient time to consider and discuss with family members…
b. Explain, if the where you plan for the consent process to take place would allow the participant to be comfortable, and have the right frame of mind to consider participation.
c. Explain how the person who would be assigned to take consent would minimize the possibility of coercion or undue influence.
d. The investigator must take precaution that in the process of obtaining consent from participants, the time and place 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.
e. The participant must also be given sufficient time to decide whether or not to participate in the research, and have the option of further discussing with their family members before making the decision.

P4. 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)?

a. If "Yes", explain:
   - Why the study requires the informed consent of a LR (e.g. participants are minors, cognitively impaired or unconscious) and
   - Relationship of the LR to the participant (e.g. spouse, parents, guardian…)
   - 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 child as defined – Persons who have not attained legal age for consent to treatments or procedures involved in the research - Under Singapore Law, this refers to individuals under the age of 21 years and not married.
     - An individual who is cognitively impaired, or
     - An individual who is unconscious.

b. No

P5. 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 precaution that in the process of obtaining consent from a research participant, it is preferable that consent be conducted in a private consultation room to ensure and protect the privacy of the participant from others' intrusion.

- The wishes of the participant must also be respected if they choose not to participate in the research.

P6. Will consent be documented in the form of a written and signed Research Participant Information Sheet and Consent Form?

- If "Yes", attach the Research Participation Information Sheet and Consent Form.

Research Participation Information Sheet and Consent Form

File Name	Description	Version Number	Version Date

- No.
- Documentation of consent will only be waived if certain conditions are fulfilled. Select the appropriate category.
  - Category A
    i. The only record linking the participant and the research would be the consent document.
    ii. The principal risk would be potential harm resulting from a breach of confidentiality.
    iii. If the research is subjected to FDA regulations, your study does not qualify for waiver of documentation of consent under Category A. (Yes or No)
    iv. Each participant would be asked whether the participant wants documentation linking the participant with the research, and the participants' wishes will govern. (No the participant would not be asked, yes the participant would be asked).
  - Category B
    i. The research presents no more than minimal risk of harm to participants.
    ii. The research involves no procedures for which written consent is normally required outside of the research context.

P7. Will research participants receive any monetary payments (including transportation allowances) or gifts for their participation in the study?

- No
- If "Yes", state the anticipated reimbursement amount (per visit and total) for travel, meal or other expenses incurred due to participation in the research (e.g. participants will be reimbursed $50 for transportation fare for each study visit).
- Payment to participants should be pro-rated and participants should not be paid only at the end of the study to minimize coercion / inducement to complete the study.

P8. Besides the Informed Consent Form, will any other materials or documents be used to explain the study to potential Research Participants (e.g. scripts, handouts, brochures, videos, log…)

- No
- Yes – attach the document(s) for review.

Document(s)

File Name	Description	Version Number	Version Date

P9. Will the Study enroll Non-English speaking participants?

- No
- Yes
  a. What are the possible languages that will be understood by the prospective participant or the legal representative?
     □ Chinese
     □ Malay
     □ Tamil
     □ Others (elaborate)
  b. Will the consent be communicated in a language that is understood by the prospective participant or the legal representative (LR)?
     - Yes
  c. How will the Non-English consent be documented?
     - Consent Document translated to the language understood by the prospective participant or the LR.
     - Attach a copy of the translated Consent Document accompanied with a Certification of Translation from the Translator or Translation Service.

Translated Document

File Name	Description	Version Number	Version Date

P10. 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 LR, if present, should be requested?

a. In emergency situations, when prior consent from the participant him/herself is not possible, the consent of the participant's LR, if present should be requested.
b. 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 regulatory requirements. The latter includes written Certification from the PI who is a Specialist and 1 independent Specialist who are not involved in the trial 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 LR within the crucial period in which treatment must be administered.
   - Neither that person or his LR nor any members of that person's family has informed the PI of his objection to that person being used as a participant in the clinical trial.
   - The participant or the participant's LR should be informed about the research as soon as possible and consent to continue should be requested.
     - Yes – Elaborate
     - No

SECTION Q: CONSENT PROCESS – CONSENT WAIVER

This section applies only to ACMS IRB Waiver of Informed Consent application.

- Informed consent will not be obtained from research participants before enrolment into the

study.

- Waiver of Informed Consent does not apply for studies that are under the regulations of the US Food and Drug Administration (FDA).
- The ACMS IRB may waive the requirement to obtain informed consent if the ACMS IRB finds that the study meets specific criteria. You need to elaborate and justify your study meets the criteria described in Section Q1 to Q4.
- The ACMS IRB may require supporting documentations or request for alternatives to waiver of informed consent in its effort to protect the participant's rights, safety, and wellbeing.

Q1. The study poses no more than minimal risk to research participants. Justify how your study meets this criterion?

- The investigator must provide the following:
  - Verification that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life.
  - Affirmation that the information collected is not sensitive in nature, and
  - Assurance that the data has been collected and are derived from standard clinically indicated procedures.

Q2. Waiver of Informed Consent will not adversely affect the rights and welfare of research participants. Justify how your study meets this criterion.

- The investigators must provide assurance that regardless of being part of the research or not, the information will still be collected as part of patients' clinically indicated procedures or as part of the normal running of business operations.
- None of the information collected would affect the clinical decisions about the individual's care, and patients are not being deprived of clinical care to which they would normally be entitled to.

Q3. The study cannot be practically conducted without the waiver of informed consent. Justify how your study meets this criterion (e.g. participants are no longer on follow-up, lost to follow-up or research).

- Investigators must assure the ACMS IRB that identifying and contacting thousands of patients / participants, although not impossible, would not be feasible for a collection of information that would not change the care they would already have received.
- In some cases, investigators must assure the ACMS IRB that it may not be feasible to contact the patients as they are no longer on follow-up, lost to follow-u or deceased.

Q4. Whenever appropriate, will the research participants be provided with additional pertinent information after participation?

- No
- Yes - elaborate

Q5. Do you have any additional comments supporting the waiver of informed consent?

- If yes, please describe.
- No.

SECTION R: RESEARCH DATA CONFIDENTIALITY

This section applies to only ACMS IRB Application.

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 form the research data.

R1. Will coded / anonymous research data be sent to the study sponsor (e.g. pharmaceutical sponsored studies)?

a. If "Yes", this would mean coded / anonymous research data will be sent to study sponsor.
- Study team would send research data to the study sponsor.

b. If "No", this would mean the research database will be created and research data stored in ACMS or institutions under the oversight of ACMS IRB.
- The study team would store all research data within the institution.
- State where the research data (soft copy / and / or hardcopy) will be stored and indicate if the location storage is secured. (i.e. Password protect PC or laptop, network or stand-alone PC, data stored in physical and allocated location with lock and key access).

c. Who will have access to the research data, and how will access to the research data be controlled and monitored?
- State the personnel who will have access to the study data e.g. PI, Co-Investigator, Study Coordinator.
- There should be limited access to the study data in order to maintain the confidentiality of the research data and participant identities.
- State how will access be controlled and monitored (e.g. research data will be kept in password-protect file or under lock and key, only study team members have access to password / key, and password changed periodically).

d. Are they any other measures in place to protect the confidentiality of the research data?
- Some measures may include password protection, security under lock and key, access controlled office…
- 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 onto a network.
- Another common protection is to code the date with an identifier, and to keep the key to the code locked in another physical location or on a separate computer.

e. Are there any research data sharing agreements with individuals or entities outside the institution, to release and share research data collected?
- No
- Yes – describe the agreement and submit a copy if available.

Agreement

File Name	Description	Version Number	Version Date

f. Describe what will happen to the research data sharing agreements with individuals or entities outside the institution, to release and share research data collected?
- No
- Yes – Describe the agreement and submit a copy of the agreement if available.

Agreement

File Name	Description	Version Number	Version Data

g. Describe what will happen to the research data when the study is completed?

- For clinical trials, according to SGGCP, the essential documents should be retained until
  - At least 2 years after the last approval of a marketing application and until there are no pending or contemplated; or
  - At least 2 years after formal discontinuation of clinical development of the investigational product; or
  - 6 years after the completion of the clinical trial.
  - For other types of research, the ACMS IRB policy recommends a minimum storage period of 6 years.
  - The length of time for which essential documents should be retained depends on the type of research and institutional policy.

R2. Will any part of the study procedures be recorded on audiotape, film / video, or other electronic medium?

a. No

b. Yes

- What is the medium (audio tape / video …) used for recording?
- Describe the contents of the recording (e.g. audio-recording of interview / focus group discussion, images of facial features…)
- Explain how the recorded information will be used in the study (e.g. photographs will be taken to assess / compare the disease condition, interviews with the participant will be audio-taped and later transcribed).
- For how long and where will the recording medium be stored? Who will have access, how will access be controlled and monitored
  - State location of storage and medium
  - 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.
- How will the recording medium be disposed?
  - Describe how the recording medium will be destroyed.

SECTION S: BIOLOGICAL MATERIALS USAGE & STORAGE

This section applies only to ACMS IRB Application.

S1. Will any biological materials (such as blood or tissue) be used in the study? This includes both prospectively collected and existing biological material. Will any part of the study procedures be recorded on audiotape, film / video, or other electronic medium?

- No
- Yes
  - State what biological materials are used and whether they are obtained prospectively or existing.

    Biological samples include, but not limited to:
    - Blood
    - Skin / buccal scrapings
    - Left over tissue from routine surgery / procedure
    - High expected rate of morbidity or mortality
    - Urine

- For prospective biological materials, describe how they are obtained. For existing biological material, state the source:

  Some examples of how samples are obtained:
  - Additional blood to be drawn during a routine blood taking by venipuncture
  - Skin / buccal scrapings
  - Fetus of patients undergoing elective / medically indicated termination of pregnancy which will be discarded otherwise

- With regard to the collection of biological materials, state (1) frequency of the collection (2) the amount collected each time and (3) the total amount collected for the research study. For example:
  - Blood is drawn from the participant at each follow-up visit
  - Approximately 20 ml of blood will be collected from the participant at each visit for a total of 3 visits.
  - The total amount of blood drawn from the participant for the entire study duration is 60 minutes.

- What tests will be performed on these biological materials?

  The tests may include the following but not limited to:
  - Genetic testing
  - Cytokines testing
  - Confirmation of diseases
  - Pharmacokinetic testing

- Will results from the tests be communicated to the participant? Elaborate>
  - Indicate if results will be conveyed to participants.
  - If not, indicate the reason(s) for not divulging the information to the participants (e.g. the information would not affect the clinical decisions about the individual's care and have no effect on the participants).

- How are the biological material identified? √ the applicable boxes.
  □ No identifiers.
  □ Biological materials are coded and the code is maintained at source.
  □ Identifiers present.
  □ Other methods – elaborate further

- Will any cell lines be created from the biological materials?
  - No
  - Yes - How will the cell lines be identified?
    - The cell lines are stripped of any identifiers and cannot be linked or traced back to its donor.
    - The cell lines are coded.
    - By other methods – elaborate

- Will the biological materials be destroyed at the completion of the study, or will they be stored for future use?

- Yes, the biological materials will be destroyed at the completion of the study.
- No, the biological materials will be stored.
  a. Where will the biological materials be stored? E.g. Biological material will be stored in XYZ lab.
  b. For how long will these biological materials be stored? E.g. the biological samples will be stored for 15 years and thereafter destroyed.
  c. What will these biological materials be used for? E.g. the biological materials will be used for further genetic testing / future related research.
  d. The Informed Consent of the participant must be obtained for storage and future use of their biological materials. The Informed Consent document must state the following"
     - Where tissue will be stored specifically (e.g. medical laboratory in NUH), how long will it be kept and how it will be disposed of,
     - Whether or not tissue samples could be provided to other researchers, institutions and commercial biomedical companies,
     - What provisions will be made to ensure privacy and confidentiality
     - Whether there is provision for withdrawal of consent for use o samples should samples are not anonymized,
     - Whether or not information about future research would be made available to the participant and / or their clinician,
     - Where possible, an indication of type or nature of research to be carried out and its implications for the participant.

     o The Informed Consent document should clearly document whether the participant agree or not to the use of their samples for future research. Only samples from participants who have consented should be stored.

     o How will these stored biological materials be identified?
       - The stored biological materials are stripped of any identifiers and cannot be linked or traced back to its donor.
       - The stored biological materials are coded,
       - By other methods – elaborate.

SECTION T: DATA & SAFETY MONITORING

This section applies only to the ACMS IRB Application.

T.1 The purpose and purpose of the Data & Safety Monitoring Plan is to ensure the safety and well-being of the participants, and the integrity of the data collected for the study.
Depending on the type of data collected and risk level of the study, this may include the PI, experts from within the department or institution, independent consultants or a combination of the said persons.

- Who is responsible for the data and safety monitoring?
  - For studies with less than minimal risks,
  - For Investigator-initiated trials, the data and safety monitoring should be by the investigator and a team of co-investigators
  - For Sponsored or Global studies, is there is a Data Safety and Monitoring Board (DSMB), a copy of the DSMB Charter should be submitted
  - A DSMB is required for complex or potentially risky studies. Factors that suggest that a DSMB is the most appropriate way to monitor data include:
    - A large study population
    - Multiple study sites
    - Highly toxic therapies or dangerous procedures
    - High expected rates of morbidity or mortality
    - High chance of early termination

  - If the DSMB / DMC is an external committee, include information / details of the composition of the external DSMB / DMC members must be submitted for reference.

DSMC / DMC Committee

File Name	Description	Version Number	Version Date

T2. Describe the frequency of review (e.g. daily, weekly, monthly or quarterly) and what data (e.g. adverse events / serious adverse events) will be monitored for safety.

T3. How is data integrity monitored to ensure that study data is authentic, accurate and complete, and if data correlates with the case report forms?

T4. Describe the stopping criteria for the research study based on efficacy, futility and safety criteria.

T5. State the route of dissemination of any data and safety information to the study sites, as well as the personal / team responsible for doing so?

OTHER ATTACHMENTS

Attach only documents that are not relevant to the above sections

SECTION U: DECLARATION OF PRINCIPAL INVESTIGATOR & ENDORSEMENT PAGE

Declaration of the Principal Investigator:

1. I will not initiate this study until I receive approval notification from ACMS IRB and regulatory authority approval (if applicable).

2. I will not initiate any change in the protocol without prior written approval from ACMS IRB, except when it is necessary to reduce or eliminate any immediate risks to the study participant. This is to be followed with the proposed amendment to the ACMS and other relevant authority for approval.

3. I will promptly report any unexpected or serious adverse events, unanticipated problems or incidents that occur in the course of this study.

4. I will maintain all relevant documents and recognize that the ACMS IRB staff and regulatory authorities may inspect these records.

5. I understand that failure to comply with all applicable regulations, institutional IRB policies and requirements may result in the suspension or termination of the study.

6. I declare that there are no existing or potential conflicts of interest for any of the study team members participating in this research study and their immediate family members. If there are, I have declared them in the relevant section of this application form.

Site	Principal Investigator	Study Role	Email	Declaration	Date

ENDORSEMENT PAGE

Department Representative Endorsement

The Department Representative can be the Head / Chief / Research Head of the PI's Department. Should the Head or Chief is the PI or Co-PI, their reporting officer should complete this Section. It is assumed that all Departments involved concur with the PI's Department Representative. The validity of this assumption rests solely with the PI. Should views differ, multiple declarations by other Department Representatives may be submitted.

1	Significance	Yes (√)	No (√)
	Does the study address an important problem? Will the study affect concepts and methods that drive the field?		
2	Approach		
	Is the conceptual framework adequately developed? Are the design, methods, and analyses adequately developed and appropriate?		
3	Innovation		
	Does the study challenge existing paradigms? Does it employ novel concepts, approaches and methods?		
4	Principal Investigator (PI)		
	Is the PI appropriately trained to conduct this study? Does the PI have evidence of commitment (e.g.		

	previous track record)?		
5	Environment		
	Is the PI's environment suited to conduct the study? Is there an adequate patient pool and are there adequate resources?		
6	Budget		
	Are the projected costs appropriate / (i.e. accurate)? Is the overall budget reasonable for this study?		
7	Time		
	Does the PI have adequate resources and time to conduct and complete the study?		
8	Comments		

I acknowledge that this research is in keeping with standards set by the PI's Department.

Date:

Full Name:

Position Head:

Department:

Institution:

The Institutional Representative has been determined by the respective Institution as the authority that declares whether your research is in keeping with the institution's research objectives, reputation and standards. The role of the Institutional Representative is not to evaluate the scientific or ethical aspects of your study, although they may offer their comments.

Comments:

I acknowledge that this research is in keeping with standards set by my institution.

Date:

Full Name:

Position Head:

	Department: Institution: