**Information on ACMS-REC Research Study Protocol Template**

This template serves as a guide for all investigators. However, it is not mandatory to use this template. Note that not all sections of this template may apply to your study. You may delete or add appropriate sections. All advisory text is highlighted. These should all be deleted before finalising the document. All sample text is in ‘basic text’ style.



**STUDY PROTOCOL**

|  |  |
| --- | --- |
| **PROTOCOL TITLE:** | |
| INSERT PROTOCOL TITLE HERE | |
|  | |
| **PROTOCOL NUMBER:** | |
| INSERT PROTOCOL NUMBER HERE | |
|  | |
| **PROTOCOL VERSION:** | Insert Version Number Here |
| **PROTOCOL DATE:** | Insert Version Date Here |
|  | |
| **PRINCIPAL INVESTIGATOR:** | |
| Insert PI Name, Designation, Institution Here | |
|  | |
| **SITE PRINCIPAL INVESTIGATOR:** | |
| Insert PI Name, Designation, Institution Here | |
| Insert PI Name, Designation, Institution Here | |
|  | |
| **CO-INVESTIGATORS:** | |
| Insert Co-Investigator Name, Designation, Institution | |
| Insert Co-Investigator Name, Designation, Institution | |
| Insert Co-Investigator Name, Designation, Institution | |
| Insert Co-Investigator Name, Designation, Institution | |

**Table of Contents**

[**1.**](#_heading=h.49x2ik5) **BACKGROUND AND RATIONALE 4**

[**2.**](#_heading=h.2p2csry) **HYPOTHESIS AND OBJECTIVES 4**

[**3.**](#_heading=h.147n2zr) **EXPECTED RIKS AND BENEFITS 4**

[**4.**](#_heading=h.3o7alnk) **STUDY POPULATION 4**

[4.1.](#_heading=h.23ckvvd) List the number and nature of subjects to be enrolled. 4

[4.2.](#_heading=h.ihv636) Criteria for Recruitment and Recruitment Process 4

[4.3.](#_heading=h.32hioqz) Inclusion Criteria 4

[4.4.](#_heading=h.1hmsyys) Exclusion Criteria 4

[**5.**](#_heading=h.41mghml) **STUDY DESIGN AND PROCEDURES/METHODOLOGY 5**

[**6.**](#_heading=h.2grqrue) **SAFETY MEASUREMENTS 6**

[6.1.](#_heading=h.vx1227) Definitions 6

[6.2.](#_heading=h.3fwokq0) Collecting, Recording and Reporting of Serious Adverse Events (SAEs) to CIRB 7

[6.3.](#_heading=h.1v1yuxt) Safety Monitoring Plan 7

[6.4.](#_heading=h.4f1mdlm) Complaint Handling 7

[**7.**](#_heading=h.2u6wntf) **DATA ANALYSIS 7**

[7.1.](#_heading=h.19c6y18) Data Quality Assurance 7

[7.2.](#_heading=h.3tbugp1) Data Entry and Storage 8

[**8.**](#_heading=h.28h4qwu) **SAMPLE SIZE AND STATISTICAL METHODS 8**

[8.1.](#_heading=h.nmf14n) Determination of Sample Size 8

[8.2.](#_heading=h.37m2jsg) Statistical and Analytical Plans 8

[**9.**](#_heading=h.1mrcu09) **DIRECT ACCESS TO SOURCE DATA/DOCUMENTS 8**

[**10.**](#_heading=h.46r0co2) **QUALITY CONTROL AND QUALITY ASSURANCE 8**

[**11.**](#_heading=h.2lwamvv) **ETHICAL CONSIDERATIONS 8**

[11.1.](#_heading=h.111kx3o) Informed Consent 9

[11.2.](#_heading=h.3l18frh) Confidentiality of Data and Patient Records 9

[**12.**](#_heading=h.206ipza) **PUBLICATIONS 9**

[**13.**](#_heading=h.4k668n3) **RETENTION OF STUDY DOCUMENTS 9**

[**14.**](#_heading=h.2zbgiuw) **FUNDING AND INSURANCE 9**

[**LIST OF ATTACHMENTS 10**](#_heading=h.1pxezwc)

**PROTOCOL SIGNATURE PAGE**

Protocol Title:

Protocol Number:

Protocol Version/ Date:

Sponsor Name:

Declaration of Investigator

I confirm that I have read the above-mentioned protocol and its attachments. I agree to conduct the described study in compliance with all stipulations of the protocol, regulations and ICH E6 Guideline for Good Clinical Practice (GCP).

|  |
| --- |
| Principal Investigator Name:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_    Principal Investigator Signature:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_    Date:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |
| --- |
| BACKGROUND AND RATIONALE |
| Briefly sketch the background to the current proposal, critically evaluating the existing knowledge and specifically identify the gaps that the project is intended to fill. State the rationale behind the proposed study design. Justify selection of target population. If applicable, reference to literature and data that are relevant to the study. |
|  |
| HYPOTHESISAND OBJECTIVES |
| Specify the hypothesis and objectives of the study. |
|  |
| 1. **EXPECTED RIKS AND BENEFITS** |
| Include expected risks and benefits to subjects. |
|  |
| STUDY POPULATION |
| List the number and nature of subjects to be enrolled. |
| Give a breakdown by institution for multi centre studies within Singapore. Indicate from where the study population will be drawn. State if there are any subject restrictions based on race of the subject. Justify the exclusion of women, children or minorities if the study tends to exclude them in context of the study design. |
| Criteria for Recruitment and Recruitment Process |
| Discuss evaluations/procedures necessary to assess or confirm whether a subject meets the eligibility criteria and may be enrolled. Describe the process of recruitment. |
| Inclusion Criteria |
| Provide a statement that subject must meet all of the inclusion criteria to participate in this study and list each criterion.   * + - 1. The disease or disorder under study, and how it is to be documented i.e. diagnostic methods, criteria for classification etc.       2. For populations with cancer or pre cancer please include requirements for histological confirmation of diagnosis, time for diagnosis and disease status at entry.       3. Demographic characteristics (e.g. gender, age). Please explain age restrictions if any       4. Ability to provide informed consent |
| Exclusion Criteria |
| Provide a statement that all subjects meeting any of the exclusion criteria at baseline will be excluded from participation and then list the criterion.  Examples include the following: medical condition or laboratory finding that precludes participation, recent (with time frame) illness that precludes or delays participation, pregnancy or lactation, characteristics of household or close contacts (e.g. household contacts who are immunocompromised), known allergic reactions to components of study product(s), treatment with another investigational drug (with time frame), history of drug/alcohol abuse, disallowed concomitant medications etc. |
|  |
| STUDY DESIGN AND PROCEDURES/METHODOLOGY |
| Describe the study design or methodology. The description should be capable of meeting the study objectives. Provide a thorough description of all study procedures, assessments and subject activities in a logical and sequential format. Include the expected duration of the study and of subject participation. Consider including a flow diagram for clarity.  Will any of the procedures be placed on the audiotape, film / video, or other electronic medium? If yes, what is the medium? Explain how the recorded information will be used? How long will the tapes etc., be retained and how will they be disposed off?  Subjects may withdraw voluntarily from participation in the study at any time. Subjects may also withdraw voluntarily from receiving the study intervention for any reason. Clearly differentiate between what evaluations are to be done in each of these circumstances.  If voluntary withdrawal occurs, the subject should be asked to continue scheduled evaluations, complete an end of study evaluation, and be given appropriate care under medical supervision until the symptoms of any adverse event resolve or the subject’s condition becomes stable. Describe efforts to continue follow - up, especially for safety outcome measures.  List possible reasons for discontinuation of study.  For particular types of studies, the following information should be considered and provided:  For Studies that collect Existing or Prospective Data   * Describe the source of the data. * Describe how the data are collected prospectively and retrospectively. * State the time period of the medical information under review. * Describe any plans for de-linking, coding or de-identifying collected information. * Describe who will have access to collected information. * Describe how long will the information be kept. * Describe plans for destroying the data or other handling once the study is completed.   For Survey Studies   * Describe interview methodology. * Describe development or selection of questionnaire. * Describe any literacy or foreign language concerns or accommodations. * Indicate whether questionnaire is validated. * Describe how questionnaire will be tested (e.g piloted). * Describe how missing or incomplete information will be handled in analysis.   Focus Group   * Describe qualifications of facilitator or individual supervising facilitation. Expectations include:   + - Prior experience facilitating groups     - Adequate knowledge of the topic     - Understands the purpose of group * Provide script or discussion questions that will be used in focus group. * Describe any literacy or foreign language concerns or accommodations. * Describe how information will be captured. * Describe how information from focus group will be presented and used. * How will focus group responses be summarized and integrated? * How will contradictory responses be handled? * Will there be thematic or qualitative coding of transcribed discussions? * Will focus group responses be used to guide the development of education materials, measures, interventions or other research procedures, publication, or inform study design? * Describe whether information drawn from focus group will be shared with group subjects. * Describe what will be done with any audio, image, video or digital records after the study is completed. |
|  |
| SAFETY MEASUREMENTS |
| Definitions |
| Serious adverse event (SAE) in relation to human biomedical research, means any untoward medical occurrence as a result of any human biomedical research which:   * results in or contributes to death * is life-threatening * requires in-patient hospitalisation or prolongation of existing hospitalisation * results in or contributes to persistent or significant disability/incapacity or * results in or contributes to a congenital anomaly/birth defect * results in such other events as may be prescribed   Adverse event (AE) in relation to human biomedical research means any untoward medical occurrence as a result of any human biomedical research which is NOT serious. Adverse event can be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease possibly/ probably/ definitely associated with the participant in the human biomedical research. |
| Collecting, Recording and Reporting of Serious Adverse Events (SAEs) to ACMS-IRB |
| Only related SAEs (definitely/ probably/ possibly) will be reported to ACMS-IRB. Related means there is a reasonable possibility that the event may have been caused by participation in the research. Please refer to the ACMS-IRB website for more information on Reporting Requirement and Timeline for Serious Adverse Events.  The investigator is responsible for informing ACMS-IRB after first knowledge that the case qualifies for reporting. Follow-up information will be actively sought and submitted as it becomes available.  Related AEs will not be reported to ACMS-IRB. However, the investigator is responsible to keep record of such AEs cases at the Study Site File. |
| Safety Monitoring Plan |
| Please include details on the Data Safety Monitoring Plan (DSMP) for the research study. Please discuss the plans in place to ensure the safety and well being of subjects, and integrity of data collected. |
| Complaint Handling |
| Briefly discuss how complaints will be handled. |
|  |
| DATA ANALYSIS |
| Data Quality Assurance |
| Discuss the measures undertaken to ensure that the data obtained from this research is accurate, complete and reliable. |
| Data Entry and Storage |
| Briefly discuss where data will be entered (i.e. will these entries be on paper or electronically), stored and handled. |
|  |
| SAMPLE SIZE AND STATISTICAL METHODS |
| Determination of Sample Size |
| Details on sample size calculation and the means by which data will be analysed and interpreted. |
| Statistical and Analytical Plans |
| * + - 1. General Considerations |
| * + - 1. Safety Analyses |
| * + - 1. Interim Analyses |
| * + - 1. Describe the types of statistical interim analyses, including their timing. |
|  |
| DIRECT ACCESS TO SOURCE DATA/DOCUMENTS |
| The investigator(s)/institution(s) will permit study-related monitoring, audits and/or IRB review and regulatory inspection(s), providing direct access to source data/document. |
|  |
| QUALITY CONTROL AND QUALITY ASSURANCE |
| Describe how data will be evaluated for adherence with the protocol and for accuracy in relation to source documents. Describe who will be responsible for the evaluation of data quality and how frequently this will be done.  If there is an independent data monitoring committee and/or steering committee or equivalent, describe the role(s), frequency of meetings and composition of the committee here. |
|  |
| ETHICAL CONSIDERATIONS |
| This study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with the Good Clinical Practice and the applicable regulatory requirements.  This final Study Protocol, including the final version of the Participant Information and Consent Form, must be approved in writing by the Academy of Chinese Medicine Singapore Institutional Research Board (ACMS-IRB), prior to enrolment of any patient into the study.  The principal investigator is responsible for informing the ACMS-IRB of any amendments to the protocol or other study-related documents, as per local requirement. |
|  |
| Informed Consent |
| Describe the procedures for obtaining and documenting informed consent of study subjects. Make provision for special populations e.g. non English speakers, children, illiterate or non-writing individuals, vulnerable populations. In obtaining and documenting informed consent, the investigator should comply with the GCP guidelines and to the ethical principles that have their origin in the Declaration of Helsinki. Please specify when consent will be taken and who will take consent.  Identify different consent forms that are needed for the study(e.g. screening, study participation, HIV screening, future use specimens, assent from minors)  If no informed consent will be taken, describe request for waiver of informed consent. |
| Confidentiality of Data and Patient Records |
| Include procedures for maintaining subject confidentiality, any special data security requirements, and record retention. This confidentiality is extended to cover testing of human biological materials and genetic tests in addition to the clinical information relating to the participating subjects. |
|  |
| PUBLICATIONS |
| State publication policy for study findings. The publication policy should cover authorship, acknowledgments, and review procedures for scientific publications. If there is a department or institution policy or agreement, the protocol can refer to it. |
|  |
| RETENTION OF STUDY DOCUMENTS |
| Records for all participants, including CRFs, all source documentation (containing evidence to study eligibility, history and physical findings, laboratory data, results of consultations, etc.) as well as IRB records and other regulatory documentation should be retained by the PI in a secure storage facility. The records should be accessible for inspection and copying by authorized authorities. Describe the retention plans for study documents. |
|  |
| FUNDING and INSURANCE |
| Provide information on funding and insurance if not addressed in a separate agreement. |

# List of Attachments

|  |  |
| --- | --- |
| ***Appendix 1*** | ***References*** |