養和醫療
HKSH Medical Group

Research Ethics Committee
Standard Operating Procedure

Revision Summary of the Last Revision

Version	Revision Details	Relevant Section	Effective Date
01	Initial release	N/A	1 September 2005
11	1. Revised format 2. Renaming from "Group Management Committee" to "HKSH Management Committee" 3. Added details of the description 4. Revised "Research Study Application Form"	Whole document Section 5.3.2, 5.4.7 Attachment 7.1	8 October 2019
12	1. Revised name from "HKSH Medical Group" or "Group" to "HKSH" 2. Updated format 3. Added SOP for monitoring of continuing/ completed clinical trials / clinical research studies 4. Updated attachment	Whole document Section 5.4.2 Attachment 7.1 & 7.3	15 August 2024

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Chairman, Research Ethics Committee
HKSH Medical Group
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Research Ethics Committee - Standard Operating Procedure

1 Objective

This Standard Operating Procedure describes the process and procedure for forming and managing a Research Ethics Committee in the HKSH Medical Group ("HKSH"). The Committee will function as an Institutional Review Board, to review and monitor proposals for research in HKSH with special attention to the needs of vulnerable human subjects.

2 Scope and Definition

2.1 The Research Ethics Committee of HKSH will review and monitor all proposals for clinical trials and other clinical research studies.

2.2 Any study involving human subjects, especially vulnerable subjects, will come under the ambit of the REC.

2.3 Terms of Reference

A. To review a principal investigator's request to conduct a clinical trial / clinical research study; such review will take into account the medical and scientific basis of the application, as well as the ethical aspects of the trial / research study.

B. To evaluate the safety of the on-going clinical trials / clinical research studies based on reports from sponsors and investigators.

C. To ensure that all the on-going clinical trials / clinical research studies are carried out in accordance with the Guideline for Good Clinical Practice issued by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), the Declaration of Helsinki of the World Medical Association (Declaration of Helsinki), the U.S. Code of Federal Regulations (if applicable) and with the applicable regulatory requirements.

D. To note any change of protocol or termination of the trial / clinical research studies.

2.4 *Abbreviations*

REC = Research Ethics Committee of HKSH

GCP = Guideline for Good Clinical Practice issued by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)–

HKSH = HKSH Medical Group

SAE = Serious Adverse Event

SOP = Standard Operating Procedure of the REC

2.5 *Definition*

Adverse Event: An adverse event is any untoward medical occurrence in a patient or clinical investigation subject who has been administered a pharmaceutical product, appliance, device or diagnostic test and which may or may not have a causal relationship with this treatment.

An adverse event may consist of a new disease, an exacerbation of a pre-existing illness or condition, a recurrence of an intermittent illness or condition, a set of related signs or symptoms, or a single sign or symptom. For spontaneous reports with marketed products, failure to produce the expected therapeutic effect is also considered to be an adverse event.

Applicable Regulatory Requirement: Any law(s) and regulation(s) addressing the conduct of clinical trials of investigational products. Conduct of clinical trials should comply with GCP and the Medicines (Clinical Trials) Regulations.

Approval: The affirmative decision of the REC that the clinical trial / clinical research has been reviewed and may be conducted at the institution site within the constraints set forth by the REC, the institution, GCP, and the applicable regulatory requirements.

Clinical Trial/ Study: Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of investigational product(s), and/or to identify any adverse reactions to investigational product(s), and/or to study the absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms *clinical trial* and *clinical study* are synonymous.

Clinical Trials Centre: A clinical research regulatory affairs centre established in HKSH to provide regulatory affairs support and monitoring of the research studies in HKSH. It serves as the centralized administrator for local, national and international clinical trials.

Investigator: A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

Informed Consent: A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

Investigator's Brochure: A compilation of the clinical and non-clinical data on the investigational product(s) which are relevant to the study of the investigational product(s) in human subjects.

Protocol: A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents.

Protocol Amendment: A written description of a change(s) to or formal clarification of a protocol.

Regulatory Authorities: The Department of Health in Hong Kong and any other bodies having regulatory power over a relevant matter.

Serious Adverse Event: A Serious Adverse Event is defined as any event which:

- is fatal
- is life-threatening (at immediate risk of death from the event as it occurred)
- is disabling or incapacitating
- requires in-patient hospitalization or prolongs a current hospitalization
- is a congenital anomaly, or
- is an event which, though not included in the above, may jeopardize the patient or may require intervention to prevent one of the outcomes listed in the above

Sponsor: An individual, company, institution, or organization which takes responsibility for the initiation, management, and/ or financing of a clinical trial or other project.

Sponsor-Investigator: An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject. The term does not include any person other an individual (e.g. it does not include a corporation or an agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.

Standard Operating Procedure: Detailed, written instructions to achieve uniformity of the performance of a specific function.

Subject: An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.

Vulnerable Subjects: Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate, These include minors and mentally incompetent persons.

3 Membership

3.1 The REC consists of the following members appointed by the HKSH Management Committee (HMC) of HKSH:

(a) at least 2 persons who are medical / pharmaceutical professionals;
(b) at least 2 persons who are not medical / pharmaceutical professionals;
(c) at least 2 persons who have legal expertise;
(d) at least 1 person each of the feminine and masculine genders; and
(e) at least 2 persons who are independent of research / clinical trial establishments.

3.2 The REC members collectively should have the qualifications and experience to review and evaluate the ethical, medical and scientific aspects of proposals for research and trials / clinical studies.

3.3 The Chairman and Deputy Chairman shall be elected by members among themselves. When the Chairman is absent or is temporarily unable to perform his duties, the Deputy Chairman shall perform the duties of the Chairman.

3.4 A member shall hold office for 3 years, and at the expiry of the term of office shall be eligible for reappointment.

3.5 The Chairman and the Deputy Chairman shall hold office for 3 years, and at the expiry of the term of office shall be eligible for re-election.

4 Training and Qualification of Members and Secretary

4.1 All members and the Secretary of the REC should attend and complete the GCP training and REC SOPs training delivered by the Clinical Trials Centre of HKSH before carrying out the REC duties. Subsequent updates of the REC SOP will be sent to all members for information. All members and the Secretary are required to sign the corresponding training record after completion of the training.

4.2 All members of the REC shall sign the conflict of interest declaration form and the statement of confidentiality regarding the REC inspected projects and all subjects' related information before discharging the REC duties.

4.3 The Secretary of the REC should be given an independent workplace as office with the necessary accessories for the routine work. Control of access to the workplace is required to ensure security of all REC documents.

5 Procedure Details

5.1 Meetings

5.1.1 The REC shall meet at least once a year.

5.1.2 At a meeting of the REC, the quorum is constituted by 50% of the full membership (being not less than 5 members), which shall include at least 1 member appointed under each of paragraphs (a), (b), (d) and (e) of subsection 3.1 hereof.

5.1.3 The Chairman, or in his absence the Deputy Chairman, shall preside at a meeting. If both the Chairman and the Deputy Chairman will be absent from a meeting, the Chairman shall appoint in advance an Acting Chairman to preside at that meeting, in default of which the members present at that meeting shall elect one among themselves as the Acting Chairman.

5.1.4 Each question to be decided at a meeting shall be decided by the majority of the members present and voting on the question.

5.1.5 The person presiding at the meeting shall ensure that each research proposal /ethical issue is fairly and thoroughly reviewed, and shall endeavour to achieve a consensus among members. If consensus cannot be reached on a question, the question shall be put to a vote. At the discretion of the presiding person, the views of a dissenting member may be recorded in the minutes and/or publicized. The minutes of the meeting shall be reviewed and approved by the REC at the next meeting.

5.1.6 On each question to be decided in a meeting, the person presiding at the meeting shall have an original vote and also, if the votes shall be equally divided, a casting vote.

5.1.7 A member who has declared conflict of interest in a matter shall neither take part in the discussion of nor vote on that matter. Subject to the discretion of the person chairing the meeting, the member may be requested to withdraw from the meeting when that matter is being considered and decided.

5.1.8 The decision of the REC on a research proposal /ethical issue shall be communicated by the Chairman to the investigator/relevant person.

5.2 Review of Applications

5.2.1 The REC will conduct reviews of applications for research proposals throughout the year, as soon as practicable after receipt of the applications and all the required documents.

5.2.2 The REC will make its decisions on the applications at scheduled regular meetings at which a quorum is present. Ad hoc meetings may be held as the REC deems necessary.

5.2.3 All communications and/or correspondence from investigators relating to applications for research proposals are to be channeled to members via the Secretary, and under no circumstances should such investigators lobby or otherwise discuss directly or indirectly with any member of the REC, unless the Chairman on behalf of the REC approaches the investigators.

5.2.4 Each year the REC shall submit an annual report of the work undertaken to HMC.

5.3 Applications for clinical trials / clinical research studies

5.3.1 The REC will review applications for clinical trials/ clinical research studies to be conducted in HKSH.

5.3.2 The principal investigator should submit:

(a) 13 sets of protocols which should include:
- Protocol and applicable amendment(s)
- Informed consent:
  - Patient information sheet
  - Written consent form and updates
  - Payment and Compensation details
- Investigator's Brochure & Available Safety & Biohazard Information
- Subject recruitment procedures
- Financial Agreement
- Documents or materials for use by subjects in the study, e.g. questionnaires

(b) 1 set of investigators' Curriculum Vitae (if not submitted to the Committee within the past 12 months)

(c) Completed Form A: Research Study Application Form (see Attachment 7.1)

(d) Abstract of the Protocol

(e) (For drug trials only) A copy of Clinical Trial Certificate issued by Department of Health.

5.3.3 Reviews of applications by the REC will be conducted throughout the year at scheduled regular meetings at a frequency as the REC determines and ad hoc review meeting as the REC deems necessary. The Chairman, Deputy Chairman or Acting Chairman may, as he deems beneficial to the review of an application/submission, request a principal investigator (or his delegate) to attend and/or present the application/submission in a review meeting.

5.3.4 The REC shall review the research proposal according to the SOP of Review of Research Application by Research Ethics Committee and provide a written notification (Attachment 7.2) to the principal investigator of its decision.

5.3.5 Any amendments to the Protocol and/or Informed Consent must be submitted to the REC for approval before the amendments are implemented, except when necessary to eliminate immediate hazards to the subjects or when the change(s) involve(s) only logistical or administrative aspects of the trial / clinical research studies (e.g. changes of monitor(s), telephone number(s)). The application should be appended with a summary of changes and a new document with tracked changes.

5.4 Monitoring of continuing/completed clinical trials / clinical research studies

5.4.1 The REC will review on-going studies at least once a year, or at shorter intervals commensurate with the degree of risk. The REC will appoint auditors for reviewing the REC approved studies. The appointed auditors should be independent of the investigators and will report to the REC for the entire auditing procedures.

5.4.2 The principal investigator is required to submit a progress report to the REC using the Research Study Progress Report Form (Attachment 7.3) once every 12 months or within three months of completion, discontinuation, termination or withdrawal of the study, whichever is sooner. REC Secretary will send the Research Study Progress Report Form to the Investigators a month before the due date for reporting.

If a prinicipal investigator does not submit the report within one month after the due date, Secretary will bring up the issue to the coming REC meeting. REC will decide on any follow-up actions, including referring the matter to the HKSH Management Committee.

The REC will authorize the Clinical Trials Centre (CTC) to perform audit on clinical trials / clinical research studies based on the submitted Research Study Progress Reports whenever necessary. CTC shall submit an audit report to REC for review.

5.4.3 Reviews of on-going studies will be conducted in REC meetings, except that an expedited review without a meeting may be conducted in the following circumstances:

1) Minor amendments without affecting the subjects' risk to benefit ratio of participating in the trial / clinical research study.
2) Research Study Progress Report
   Based on the results of the review, the REC will provide a written reply to the principal investigator, with conditional clause(s) for protocol compliance and/or reporting at a shorter interval for observation when deem necessary.

For 1), expedited review is conducted by Chairman and Deputy Chairman. If either one of Chairman and Deputy Chairman is absent, a member will be designated for the purpose.

For 2), expedited review is conducted by a member designated by Chairman.
The result(s) of the expedited review will be reported to members at the next REC meeting.

A full review shall be conducted in the following circumstances:

i) The opinion from the expedited review is negative.
ii) The opinions from two committee members are dissenting.
iii) Member(s) of the REC deemed it necessary to conduct a full review.

5.4.4 All SAEs will be reviewed by all members of the REC. The principal Investigator is required to submit a Serious Adverse Event(SAE) Report Form(Attachment 7.4) to the REC. The REC secretary will forward all the SAEs to REC members by e-mail for immediate notification and review. Ad hoc meetings will be held or any actions listed in 5.4.7 will be taken as the REC deems necessary. All SAEs will be reported at the next REC meeting. A written reply from the REC will be given to the principal investigator after the Meeting.

5.4.5 The principle investigator should promptly report the following matters to the REC:

(a) Deviations from, or changes/amendments of the protocol to eliminate immediate hazards to the trial / study subjects.
(b) Changes increasing the risk to subjects and/or affecting significantly the conduct of the trial/ study
(c) All SAEs and safety updates.
(d) Updates of Investigator's Brochure and any new information that may affect adversely the safety of the subject or the conduct of the trial / study.

5.4.6 The Chairman or Deputy Chairman or a member designated will conduct a review on any matters set out in 5.4.5 hereof and the reports submitted under 5.4.2 hereof to see whether any rectification/remedial/modification action(s) listed in 5.4.7 hereof is required.

If any such action is required, the REC will notify the Principal Investigator in writing within fourteen (14) calendar days after the decision is made.
If there is no concern or comment on the new information, an acknowledgement of receipt of the submission will be issued to the principal investigator.

5.4.7 Rectification / Remedial / Modification Actions

The REC may:

(a) Request the Principal investigator to take appropriate rectification, remedial and/or modification action(s) with respect to the deviation/incident within fourteen (14) calendar days after notification;
(b) Request the suspension of further recruitment of subjects into the study until the required rectification/remedial/modification action(s) has/have been completed; and/or
(c) Request for suspension or termination of the study if the required rectification/remedial/modification action(s) is/are not completed within a reasonable period of time, or if the deviation/incident is deemed by the REC as seriously affecting the rights, safety or well-being of the subjects and the deviation/incident is not rectifiable/remediable/modifiable.

5.5 Eligibility of investigators

The REC will consider the eligibility of the investigators of the proposed trials with reference to their qualifications set out in their current curricula vitae and/or any other relevant documentation the REC requests.

5.6 Informed Consent

5.6.1 Prior to the beginning of the trial / study, the investigator should have the REC's written approval of the written informed consent form and any other written information to be provided to subjects. The GCP requirements for informed consent of trial subjects are described in detail in the GCP. The investigator is required to complete the “Informed Consent Checklist” at Appendix A of Form A: Research Study Application Form (Attachment 7.1) when submitting the protocol for REC approval.

5.6.2 The REC will review both the amount and method of payment, if any, to subjects to ensure that neither presents problems of coercion or undue influence on the trial / study subjects. Payments to a subject should be prorated and not wholly contingent on completion of the trial / study by the subject. Methods, amount and schedule of payment to trial / study subjects, if any, should be included in the written consent form and any other written information to be provided to subjects.

6 Records

6.1 The REC Secretary shall maintain and retain the following records:

(a) Written procedures
(b) Membership lists & curricula vitae of members
(c) Minutes of meetings
(d) Correspondence
(e) A permanent file containing all the records of each submitted proposal. These records will include, but may not be limited to:
- Research proposal
- REC's decisions
- Records of periodic review

6.2 Written procedures and membership lists will be made available to HMC, Investigators or Sponsors and authorized personnel of the Government.

6.3 All records related to research proposals will be retained according to SOP of Records Management for Research Ethics Committee.

6.4 The following records shall be retained by the respective persons for the duration set out below:

No.	Record	Retention Period	Retained by
1.	Form A – Research Study Application Form	7 years	Secretary
2.	Written Notification	7 years	Investigator
3.	Research Study Progress Report Form	7 years	Secretary
4.	Research Study Approval Form	7 years	Secretary

7 Attachments

7.1 Form A – Research Study Application Form

7.2 Written Notification

7.3 Research Study Progress Report Form

7.4 Serious Adverse Event (SAE) Report Form

8 Reference Documents

8.1 Research Ethics Committee. *Standard Operating Procedure for Membership Formation for Research Ethics Committee*. (A.2.3.6.1-RESEC-RESEC-H-PC)

8.2 Research Ethics Committee. *Standard Operating Procedure for Recruitment of Independent Consultant or Contractor for Research Review for Research Ethics Committee*. (A.2.3.6.2-RESEC-RESEC-H-PC)

8.3 Research Ethics Committee. *Standard Operating Procedure for Review of Research Application for Research Ethics Committee*. (A.2.3.6.3-RESEC-RESEC-H-PC)

8.4 Research Ethics Committee. *Standard Operating Procedure for Complaint Management for Research Ethics Committee*. (A.2.3.6.4-RESEC-RESEC-H-PC)

8.5 Research Ethics Committee. *Standard Operating Procedure for Records Management for Research Ethics Committee*. (A.2.3.6.5-RESEC-RESEC-H-PC)

9 Revision of SOP

This SOP will be reviewed on a two-yearly basis by the REC to decide if any alterations are needed. The SOP will be revised after the biennial review if needed.

Attachment 7.1 (P.1/9)

Form A – Research Study Application Form

Research Study Application Form

For official use only:
Ref. No:_____

PART I: Study Description

1. Title of Study

2. Principal Investigator

Name	Designation	Department/Division

Please attach curriculum vitae.

3. Co-investigators

Name	Designation	Department/Division

Please attach curriculum vitae

4. Duration of Study

4.1 Proposed study starting date: _____ /_____ /_____ (dd/mm/yyyy)

4.2 Proposed study completion date: _____ /_____ /_____ (dd/mm/yyyy)

4.3 Proposed study records retention period after study completion/termination:_____ (Year(s))

5. Participants

5.1 Is the study done in collaboration with other units/institutions? ☐ Yes ☐ No

5.2 If so, please specify which unit/institution:

_____

Research Study Application Form

6. Brief summary of study (use language understandable by a lay person)

7. Aim of the Study and Expected Outcome

8. Study Design & Methodology

8.1 For Non-experimental / Observational study

- ☐ Prospective, observational study
- ☐ Retrospective, chart review study
- ☐ Other, specify: _____

8.2 For Prospective, Experimental Study

- ☐ Randomized controlled trial
- ☐ Non-randomized controlled trial
- ☐ Uncontrolled trial
- ☐ Other, specify: _____

Research Study Application Form

9. Research Plan and Methodology

Attach the research protocol instead, if available

10. Study Subjects

10.1 How many subjects will be recruited locally? Explain rationale for sample size calculation if possible.

10.2 How will subjects (patients/controls) be identified and recruited?

10.3 What are the inclusion and exclusion criteria?

10.4 If randomization is used, explain the process:

Research Study Application Form

PART II: EXPERIMENTAL STUDY

11. Product/Procedure: Drug, Appliance, Device or Diagnostic Test

11.1 Will any product be administered to subjects for the purpose of this study? ☐Yes ☐No ☐N/A

i.e. in addition to treatment the subjects would receive if not participating in research

☐ Drug. The drug trial is Phase_____

☐ Medical device

☐ Others: _____

11.2 Is this study sponsored by industry/commercial agency? ☐Yes ☐No ☐N/A

If yes, specify nature of sponsorship:

11.3 Is the product licensed in Hong Kong? ☐Yes ☐No ☐N/A

11.4 Is the product licensed in other countries? ☐Yes ☐No ☐N/A

11.5 Is the product being studied for licensed indications? ☐Yes ☐No ☐N/A

11.6 Has the procedure been undertaken before elsewhere? ☐Yes ☐No ☐N/A

If yes, please give short description:

11.7 Is there a plan to apply for a clinical trials certificate? ☐Yes ☐No ☐N/A

Research Study Application Form

12. Benefits, potential hazards and risks to study subjects

12.1 State possible benefits to study subjects:

12.2 Describe potential discomfort, distress and hazards entailed by study procedures, and how these will be minimized:

13. Financial costs and payment to subjects

13.1 Will there be any financial cost to the subjects? ☐Yes ☐No ☐N/A

13.2 Will the subjects receive payment or other benefits? ☐Yes ☐No ☐N/A

If yes, specify nature and amount:

14. Indemnity and Compensation

14.1 Is there an external indemnity/insurance provided? ☐Yes ☐No ☐N/A

14.2 Is the indemnity supported by an insurance policy? ☐Yes ☐No ☐N/A

14.3 If yes, is an insurance certificate available for review? ☐Yes ☐No ☐N/A

.....

Research Study Application Form

PART III

15. Confidentiality, consent and research ethics

15.1 What measures are taken to protect the identity of the subjects?

15.2 Will a written informed consent be obtained from study subjects? ☐Yes ☐No ☐N/A

If "yes", please attach a copy of consent form in English and one in Chinese

15.3 Has the research project been submitted for review to an external Ethics Committee? ☐Yes ☐No ☐N/A

If yes, specify which Committee:

16. Source of Funding (external), Resources Implication and Conflict of Interest

16.1 Research Fund: ☐ Company Sponsored ☐ No Funding ☐ Other

If "other", specify:

16.2 Is there any payment to the investigator or study site for conducting the study?

PART IV: OTHER CONSIDERATIONS

17. Are there any other types of assistance required?

Statistical support	☐ specify:	_____
Clerical	☐ specify:	_____
I.T.	☐ specify:	_____
Financial support	☐ specify:	_____
Other	☐ specify:	_____

Research Study Application Form

PART V: DECLARATIONS

Declaration by Investigators

1. The information supplied is to the best of my/our knowledge and belief accurate.
2. I/We shall comply with the principles enunciated in the 1996 or a later version of the Declaration of Helsinki, the Good Clinical Practice and whenever applicable the U.S. Code of Federal Regulations.
3. I/We understand that approval by the HKSH Medical Group Research Ethics Committee (REC) / Research Committee (RC) shall be renewed every 12 months and that the project can be stopped by the REC/RC at any time before the end of the study if the protocol is not strictly adhered to.
4. I/We agree to report study progress to the REC/RC as requested, and to submit a final report at the end of the project.
5. I/We agree to report all serious adverse events to the Hospital Management as soon as these are discovered.
6. I/We agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments.
7. I/We agree to maintain adequate accurate records and to make them available for audit/ inspection.
8. I/We undertake to adhere strictly to the research protocol.
9. I/We agree that due acknowledgment will be made to HKSH Medical Group in any publication of the results of the Research Study.
10. I/We undertake to take all reasonable steps to keep all information confidential and secure and

	Name	Signature	Date
Principal Investigator:			
Co-investigators:			

Appendix A: INFORMED CONSENT CHECKLIST

Please indicate where the following items may be found.

	Patient Information Sheet	Consent Form	Not Included
That the trial involves research and those aspects of the trial that are experimental			
The purpose of the trial			
The trial treatment(s) and the probability for random assignment to each treatment			
The subject's responsibilities			
The trial procedures to be followed, including all invasive procedures			
The reasonably foreseeable risks or inconveniences to the subject and when applicable, to an embryo, foetus, or nursing infant			
The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this			
The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks			
The compensation and/or treatment available to the subject in the event of trial-related injury			
The anticipated pro-rated payment, if any, to the subject for participating in the trial			
The anticipated expenses, if any, to the subject for participating in the trial			
That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled			
That the monitor (s), and REC will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access.			
That records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and /or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential			

Attachment 7.1 (P.9/9)

Form A – Research Study Application Form

That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial			
The person(s) to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury			
The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated			
The expected duration of the subject's participation in the trial			
The approximate number of subjects involved in the trial			
That the Investigator includes the statement "The Institution will receive payment to cover the administrative costs and trial related expense" or similar			

Attachment 7.2 (P.1/2)
Written Notification

Date:
Investigator's Address

Dear Investigator,

RE: APPLICATION TO CONDUCT RESEARCH IN THE HKSH MEDICAL GROUP
Protocol Title
Protocol Number
Date of review

We refer to your application of date.

We are pleased/ regret to inform you that the Research Ethics Committee has approved / not approved for the proposed study titled above to be carried out in the HKSH Medical Group. The Approval Form is attached.

Please note the following conditions:

1. A Clinical Trial Certificate is required for this study (delete if not required)
2. No subjects may be involved in any study procedure prior to the REC approval date or after the expiration date.
3. Any serious adverse events must be reported to the REC promptly.
4. All protocol modifications must be REC approved prior to implementation unless they are intended to reduce risk.
5. All protocol deviations must be reported to the REC promptly.
6. All recruitment materials and methods must be approved by the REC prior to being used.
7. Report study progress to the REC annually until study closure. You are required to submit a progress report to the Committee using the Study progress/Final Report form once every 12 months or within three months of completion, discontinuation, termination or withdrawal of the study, whichever is sooner. The REC secretary will send the Study progress/Final Report form to the Investigators a month before due date of each study
8. The Committee will authorize the Clinical Trials Centre (CTC) to perform audit on study based on the submitted Study progress/Final Reports whenever necessary.

Thank you very much.

Yours sincerely,

Chairman, Research Ethics Committee
HKSH Medical Group

Please quote REC Ref. No: _____in future correspondence with the Committee

Attachment 7.2 (P.2/2)
Written Notification

RESEARCH ETHICS COMMITTEE OF THE HKSH MEDICAL GROUP

APPROVAL FORM

The _____
(Name of Research Ethics Committee)

decided at its meeting on _____ to give APPROVAL
(Date of Meeting)

for the _____-sponsored trial to be conducted by
(Sponsor)

_____ at HKSH Medical Group
(Principal Investigator) *(Site where trial will be conducted)*

The following documents were reviewed and approved:

Protocol Title: _____

_____

Protocol Identification:

Number: _____ Version: _____ Date: _____

Protocol Amendment Number/Version: _____ Date _____

Protocol Amendment Number/Version: _____ Date: _____

Patient Information Sheet Version: _____ Date: _____

Consent Form in English Version: Version

Date: _____

Consent Form in Chinese Version: Version

Date: _____

Investigator Brochure Version: Version Date: _____

Other: (please describe e.g. advertisement; Investigator's Brochure)

(1) _____

This Independent Research Ethics Committee is organized and operates according to Declaration of Helsinki, GCP and the applicable laws and regulations.

_____ _____ _____
Name Signature Date
REC Chairperson/Designee

Attachment 7.3 (P.1/2)

Research Study Progress Report Form

RESEARCH STUDY PROGRESS REPORT FORM

PART I: Research Identification

Title of Study

Title of Study	
Protocol no.	

Principal Investigator

Name	Designation	Department/Division

Duration

Study Start Date	Anticipated End Date
_____/_____/_____	_____/_____/_____

PART II: Progress Report

Report period	From _____/_____/_____ to _____/_____/_____		
Planned sample size (local)		No. recruited	
No. completed study		No. withdrew	
Withdrawal reasons:			

PART III: Changes on Protocol

Study protocol change	☐ No ☐ Yes
Investigator change	☐ No ☐ Yes
Have they been reported?	☐ No ☐ Yes (If no, please attach application for the change)

PART IV: Summary of Serious Adverse Events

Is there any Serious Adverse Event of the study?	☐ No ☐ Yes
Does the Serious Adverse Event affect the study?	☐ No ☐ Yes, please specify _____ _____ _____ _____

Attachment 7.3 (P.2/2)

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PART V: Summary of Complaints from Subjects

Is there any complaint from the subjects?	☐ No ☐ Yes, please specify _____ _____ _____

PART VI: Updated Information

Is the 'Certificate of Insurance' of the study still valid? **Please attach renewed 'Certificate of Insurance' if the present one is expired.**	☐ No ☐ Yes ☐ Not applicable

PART VII: Current Progress of Study

Continue according to the plan	☐ No ☐ Yes
Extend study period	☐ No ☐ Yes, please specify the anticipated end date ____ / ____ / _____
Premature termination	☐ No ☐ Yes, please specify the reason _____
Ended according to the plan	☐ No ☐ Yes , please specify the end date _____/ _____/ _____ and provide a final report, and the document storage information: _____
Clinical Improvement	☐ No ☐ Not applicable ☐ Yes (Plan for implementation / Implemented / Not Implemented (Please circle))
Plan for publication and/ or conference presentation	☐ No ☐ Yes*
Study was published	☐ No ☐ Yes*
Remarks:	

*Please attach a copy of publication when available

Report by:

Name	Signature	Date

RESEC.002.H/E-04-082024

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養和醫療集團成員 A member of HKSH Medical Group

Attachment 7.4 (P.1/2)
Serious Adverse Event (SAE) Report Form

HKSH Medical Group Research Ethics Committee (REC)
Serious Adverse Event (SAE) Report Form

For REC Use:
Date received: _____ *(dd/mm/yy)*
Application Reference No.: _____

1. Basic Information

Study title			
REC Ref. No.		Protocol no.	
Study start date		Anticipated end date	
Maximum number of subjects/samples/records planned (local)			

2. Study Site(s) Involved

☐ Overseas site(s) (Submit report(s) from sponsor and omit section 3-5)

☐ Local site(s) Name of study site: ☐

3. Subject Outcome at Time of Report

☐ Complete recovery ☐ Recovery with sequelae ☐ Events not yet resolved

☐ Unknown ☐ Death; cause: ☐

4. Serious Adverse Events

Subject reference: Code ☐ Initials ☐ Age ☐ Sex ☐

Relevant medical history & current treatments:	
Nature of SAE: *(Describe temporal relationship with intervention & other concomitant therapies)*	

SAE start date ☐ SAE stop date ☐ /not resolved*

Type of SAE ☐ initial ☐ follow up

Frequency ☐ One episode ☐ Intermittent ☐ Continuous

Attachment 7.4 (P.2/2)
Serious Adverse Event (SAE) Report Form

Seriousness	☐ Death	☐ Life threatening
	☐ Significant disability/incapacity	☐ Required hospitalisation
	☐ Persistent disability/incapacity	☐ Prolonged hospitalisation
	☐ Congenital anomaly/birth defect	☐ None of the above
	☐ Other medically important condition	

5. Suspected relationship to Study

☐ Definite ☐ Probable ☐ Possible ☐ Not related ☐ Not assessable

6. Remedial actions

On the affected subject:	☐ None	☐ Adjusted dosage
	☐ Interrupted temporarily	☐ Discontinued/ terminated study
For all subjects/ study design:		

Report by

Name	Signature	Date