



養和醫療
HKSH Medical Group

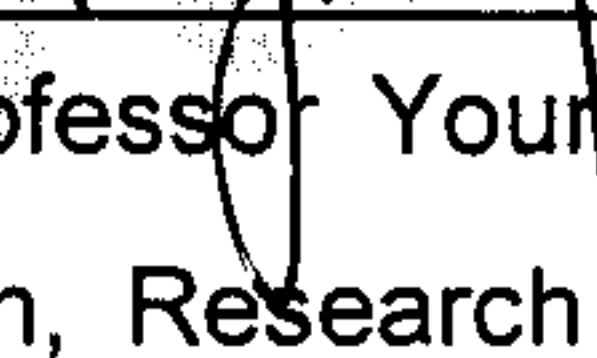
Research Ethics Committee Standard Operating Procedure

Revision Summary of the Last Revision

Version	Revision Details	Relevant Section	Effective Date
01	Initial release	N/A	1 September 2005
10	Restructure of the contents in REC SOP, to keep consistency between operation and REC SOP	Whole document	11 April 2019
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

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 Professor Young Tse Tse, Rosie
 Chairman, Research Ethics Committee
 HKSH Medical Group
 8 October 2019

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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 ("the Group"). The Committee will function as an Institutional Review Board, to review and monitor proposals for research in the Group with special attention to the needs of vulnerable human subjects.

2. Scope and Definition

2.1 The Research Ethics Committee of the Group 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 the HKSH Medical Group
 GCP = Guideline for Good Clinical Practice issued by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)–
 The Group = 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 the Group to provide regulatory affairs support and monitoring of the research studies in the Group. 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 than 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 the Group:
- (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 the Group 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 the Group.

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. The REC Secretary will send the Research Study Progress Report Form to the Investigators a month before the due date for reporting.
- 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/yy)
4.2	Proposed study completion date: _____ / _____ / _____ (dd/mm/yy)

5. Participants

5.1	Is the study done in collaboration with other units/institutions? <input type="checkbox"/> Yes <input type="checkbox"/> No
5.2	If so, please specify which unit/institution: _____

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Research Study Application Form

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

Attachment 7.1 (P.2/9)**Form A – Research Study Application Form****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 <input type="checkbox"/> Prospective, observational study <input type="checkbox"/> Retrospective, chart review study <input type="checkbox"/> Other, specify: _____
8.2	For Prospective, Experimental Study <input type="checkbox"/> Randomized controlled trial <input type="checkbox"/> Non-randomized controlled trial <input type="checkbox"/> Uncontrolled trial <input type="checkbox"/> Other, specify: _____

9. Research Plan and Methodology

Attach the research protocol instead, if available

Attachment 7.1 (P.3/9)**Form A – Research Study Application Form****Research Study Application Form****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:

Attachment 7.1 (P.4/9)

Form A – Research Study Application Form



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? <i>i.e. in addition to treatment the subjects would receive if not participating in research</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
	<input type="checkbox"/> Drug. The drug trial is Phase _____ <input type="checkbox"/> Medical device <input type="checkbox"/> Others: _____	
11.2	Is this study sponsored by industry/commercial agency?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
	If yes, specify nature of sponsorship:	
11.3	Is the product licensed in Hong Kong?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
11.4	Is the product licensed in other countries?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
	If yes, specify where:	
11.5	Is the product being studied for licensed indications?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
11.6	Has the procedure been undertaken before elsewhere?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
	If yes, please give short description:	
11.7	Is there a plan to apply for a clinical trials certificate?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA

Attachment 7.1 (P.5/9)**Form A – Research Study Application Form****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 minimised:

13. Financial costs and payment to subjects

13.1	Will there be any financial cost to the subjects?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
13.2	Will the subjects receive payment or other benefits?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
If yes, specify nature and amount:		

14. Indemnity and Compensation

14.1	Is there an external indemnity/insurance provided?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
14.2	Is the indemnity supported by an insurance policy?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
14.3	If yes, is an insurance certificate available for review?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA

Attachment 7.1 (P.6/9)

Form A – Research Study Application Form



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?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA <i>If "yes", please attach a copy of consent form in English and one in Chinese</i>
15.3	Has the research project been submitted for review to an external Ethics Committee?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
	If yes, specify which Committee:	

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

16.1	Research Fund:	Company Sponsored <input type="checkbox"/>	No Funding <input type="checkbox"/>
		Other <input type="checkbox"/>	
	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	<input type="checkbox"/> specify:	
Clerical	<input type="checkbox"/> specify:	
I.T.	<input type="checkbox"/> specify:	
Financial support	<input type="checkbox"/> specify:	
Other	<input type="checkbox"/> specify:	

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Research Study Application Form

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

Attachment 7.1 (P.7/9)**Form A – Research Study Application Form****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 that all data collected is for the purpose of research study only.

	Name	Signature	Date
Principal Investigator:			
Co-investigators:			

Attachment 7.1 (P.8/9)**Form A – Research Study Application Form****Research Study Application Form****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.			

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Research Study Application Form

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Attachment 7.1 (P.9/9)**Form A – Research Study Application Form****Research Study Application Form**

	Patient Information Sheet	Consent Form	Not Included
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			
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 _____
(Principal Investigator) HKSH Medical Group
(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
REC Chairperson/Designee

Signature

Date

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	<input type="checkbox"/> No <input type="checkbox"/> Yes
Investigator change	<input type="checkbox"/> No <input type="checkbox"/> Yes
Have they been reported?	<input type="checkbox"/> No <input type="checkbox"/> 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?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Does the Serious Adverse Event affect the study?	<input type="checkbox"/> No <input type="checkbox"/> Yes, please specify <div style="border-bottom: 1px solid black; height: 15px; margin-top: 5px;"></div> <div style="border-bottom: 1px solid black; height: 15px; margin-top: 5px;"></div> <div style="border-bottom: 1px solid black; height: 15px; margin-top: 5px;"></div>

Attachment 7.3 (P.2/2)

Research Study Progress Report Form



RESEARCH STUDY PROGRESS REPORT FORM

PART V: Summary of Complaints from Subjects

Is there any complaint from the subjects?	<input type="checkbox"/> No <input type="checkbox"/> Yes, please specify <hr style="border: 0; border-top: 1px solid black; margin: 2px 0;"/> <hr style="border: 0; border-top: 1px solid black; margin: 2px 0;"/>
---	---

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.	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable
--	--

PART VII: Current Progress of Study

Continue according to the plan	<input type="checkbox"/> No <input type="checkbox"/> Yes
Extend study period	<input type="checkbox"/> No <input type="checkbox"/> Yes, please specify the anticipated end date ____ / ____ / ____
Premature termination	<input type="checkbox"/> No <input type="checkbox"/> Yes, please specify the reason <hr style="border: 0; border-top: 1px solid black; margin: 2px 0;"/>
Ended according to the plan	<input type="checkbox"/> No <input type="checkbox"/> Yes, please specify the end date ____ / ____ / ____ and provide a final report
Clinical Improvement	<input type="checkbox"/> No <input type="checkbox"/> Not applicable <input type="checkbox"/> Yes (Plan for implementation / Implemented / Not Implemented (Please circle))
Plan for publication and/ or conference presentation	<input type="checkbox"/> No <input type="checkbox"/> Yes*
Study was published	<input type="checkbox"/> No <input type="checkbox"/> Yes*
Remarks:	

*Please attach a copy of publication when available

Report by:

Name	Signature	Date

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	<input type="checkbox"/> initial	<input type="checkbox"/> follow up		
Frequency	<input type="checkbox"/> One episode	<input type="checkbox"/> Intermittent	<input type="checkbox"/> 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 ☐ None ☐ Adjusted dosage
 subject: ☐ Interrupted temporarily ☐ Discontinued/ terminated study

For all subjects/
 study design:

--

Report by

Name	Signature	Date



養和醫療
HKSH Medical Group

Standard Operating Procedure for Membership Formation for Research Ethics Committee

Revision Summary of the Last Revision

Version	Revision Details	Relevant Section	Effective Date
01	Initial release	N/A	17 July 2018
02	Restructure of the contents in REC SOP, to keep consistency between operation and REC SOP	Whole document	11 April 2019
03	1. Revised format 2. Renaming from "Group Management Committee" to "HKSH Management Committee"	Whole document	8 October 2019

Document Locations and Distribution if any

Controlled Soft Copy	Policy Portal in HKSH Medical Group
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Professor Young Tse Tse, Rosie
Chairman, Research Ethics Committee
HKSH Medical Group
8 October 2019

Prepared by : Research Ethics Committee
Approved by Chairman : 08/10/2019
First Issued : 17/07/2018
Last Revised : 11/04/2019
Reviewed : Refer to Content Page
Risk Rating : N/A

Standard Operating Procedure for Membership Formation for Research Ethics Committee

1 Objective

This Standard Operating Procedure (SOP) sets out the process and procedure for forming and managing a Research Ethics Committee (REC) in the HKSH Medical Group (“the Group”).

2 Scope and Definition

Not Applicable

3 Responsibility

Not Applicable

4 Training and Qualification

Not Applicable

5 Procedure Details

5.1 Appointment of Members

5.1.1 Members are invited and appointed by the HKSH Management Committee (HMC) of the Group.

5.1.2 Members are selected on the basis of maturity, experience and expertise. The 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 research studies.

5.1.3 The REC shall consist of at least 10 members, including:

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

5.2 Election of Chairman and Deputy Chairman

5.2.1 The Chairman and Deputy Chairman shall be elected by members among themselves.

5.3 Terms of office

- 5.3.1 A member shall hold office for 3 years, and at the expiry of the term of office shall be eligible for reappointment.
- 5.3.2 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.
- 5.3.3 In the event of resignation or death of a member, HMC of the Group will appoint a member to serve the unexpired portion of the resigning/deceased member's term.

6 Record

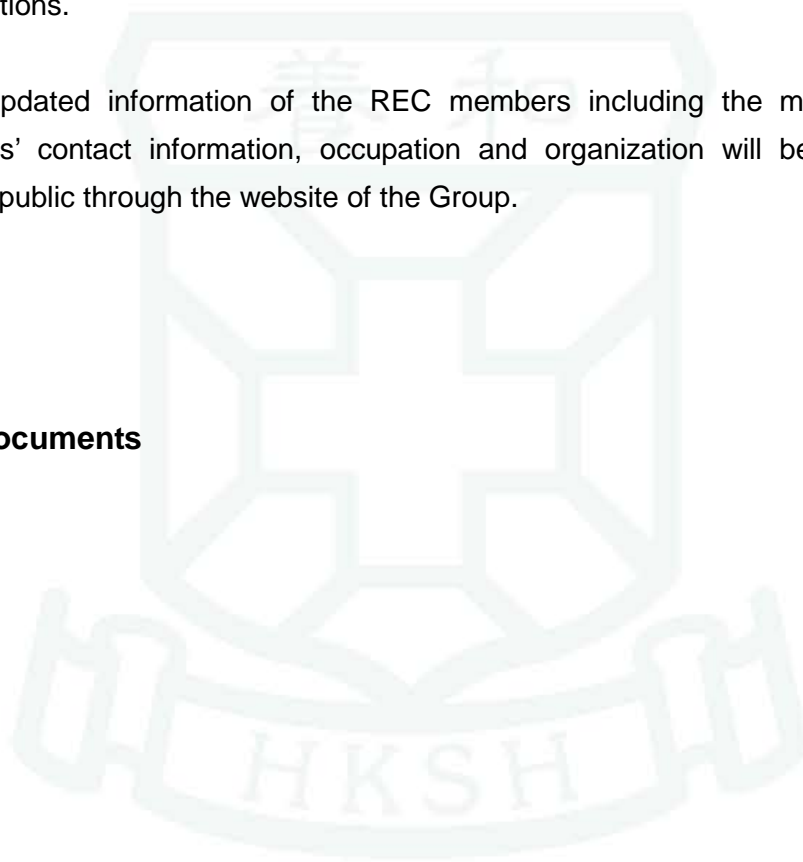
- 6.1 The REC Secretary is required to maintain an updated list of REC members and their qualifications.
- 6.2 All the updated information of the REC members including the membership list and members' contact information, occupation and organization will be publicized to the general public through the website of the Group.

7 Attachment

Not Applicable

8 Reference Documents

Not Applicable





養和醫療
HKSH Medical Group

Standard Operating Procedure for Recruitment of Independent Consultants or Contractors for Research Review by Research Ethics Committee

Revision Summary of the Last Revision

Version	Revision Details	Relevant Section	Effective Date
01	Initial release	N/A	17 July 2018
02	Restructure of the contents in REC SOP, to keep consistency between operation and REC SOP	Whole document	11 April 2019
03	Revised format	Whole document	8 October 2019

Document Locations and Distribution if any

Controlled Soft Copy	Policy Portal in HKSH Medical Group
-----------------------------	-------------------------------------

Professor Young Tse Tse, Rosie
Chairman, Research Ethics Committee
HKSH Medical Group
8 October 2019

Prepared by : Research Ethics Committee Members
Approved by Chairman : 08/10/2019
First Issued : 17/07/2018
Last Revised : 11/04/2019
Reviewed : Refer to Content Page
Risk Rating : N/A

Standard Operating Procedure for Recruitment of Independent Consultants or Contractors for Research Review by Research Ethics Committee

1 Objective

This Standard Operating Procedure (SOP) sets out the procedures for recruiting independent consultants or contractors for research review by the Research Ethics Committee (REC).

2 Scope and Definition

According to section 3.2.6 of the Guideline for Good Clinical Practice issued by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), an REC may invite non-members with expertise in special areas for assistance. This SOP is applicable to the recruitment of independent consultants and contractors for research review by the REC.

3 Responsibility

The REC is responsible for the engagement and management of REC's independent consultants / contractors for research review.

4 Training and Qualification

Not Applicable

5 Procedure Details

When remuneration to independent consultants / contractors is required for service delivery, the REC should forward the request of service to HKSH Management Committee which will follow the HKSH Medical Group's procedure for requisition for fixed asset / valuable items or purchase of service rendered by external contractors.

6 Record

Not Applicable

7 Attachment

Not Applicable

8 Reference Documents

Not Applicable



養和醫療
HKSH Medical Group


Standard Operating Procedure for Review of Research Application for Research Ethics Committee

Revision Summary of the Last Revision

Version	Revision Details	Relevant Section	Effective Date
01	Initial release	N/A	17 July 2018
02	Restructure of the contents in REC SOP, to keep consistency between operation and REC SOP	Whole document	11 April 2019
03	Revised format	Whole document	8 October 2019

Document Locations and Distribution if any

Controlled Soft Copy	Policy Portal in HKSH Medical Group
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 Professor Young Tse Tse, Rosie
 Chairman, Research Ethics Committee
 HKSH Medical Group
 8 October 2019

Prepared by : Research Ethics Committee Members
 Approved by Chairman : 08/10/2019
 First Issued : 17/07/2018
 Last Revised : 11/04/2019
 Reviewed : Refer to Content Page
 Risk Rating : N/A

Standard Operating Procedure for Review of Research Application by Research Ethics Committee

1 Objective

This Standard Operating Procedure (SOP) sets out the standard procedure of the Research Ethics Committee (REC) of the HKSH Medical Group (“the Group”) for reviewing research study applications.

2 Scope and Definition

This SOP is applicable to the review of research study applications submitted to the REC.

3 Responsibility

3.1 REC members are responsible for reviewing research study applications.

3.2 The REC Secretary is responsible for submitting research study applications to the REC for review.

4 Training and Qualification

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 the Group before carrying out the REC duties. Subsequent updates of the REC SOP will be sent to all members for information.

5 Procedure Details

5.1 Meetings for review of research study applications

5.1.1 At a meeting of the REC for review of a research study application, 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) (medical / pharmaceutical professionals), (b) (not medical / pharmaceutical professionals), (d) (feminine and masculine genders) and (e) (persons independent of research / clinical trial establishments) of subsection 3.1 of the REC SOP.

5.1.2 The Chairman, or in his absence the Deputy Chairman, shall preside at the meeting. If both the Chairman and the Deputy Chairman will be absent from the 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.

5.1.3 The Chairman, Deputy Chairman or Acting Chairman may, if he deems beneficial to the review of the application/submission, request the principal investigator (or his delegate) to attend the meeting and/or present the application/submission.

5.1.4 The REC may engage the assistance of external consultants with expertise in special areas, and may invite such consultants to attend the meeting. Such consultants shall sign the conflict of interest declaration form and the statement of confidentiality regarding the REC inspected projects and all subjects' related information. However, such consultants can only give their opinions at the request of members, and must not take part in the discussions or decisions of the REC.

5.2 Preliminary Review before Meeting

5.2.1 The REC Secretary shall send the application documents together with the Response Form (Attachment 7.1) to REC members for preliminary review at least 7 calendar days before the review meeting. Each member shall indicate on the Response Form whether he endorses the proposed research study protocol or has queries / comments.

5.2.2 If queries / comments are raised by members, the principal investigator should be requested to provide a written response before the review meeting, or prepare materials to respond in the meeting.

5.2.3 All members of REC shall make a declaration of conflict of interest (Attachment 7.2). A member who has declared a conflict of interest must withdraw from the review of the application and return the application documents to the REC Secretary.

5.3 Review in Meeting

5.3.1 The Chairman, Deputy Chairman or Acting Chairman should facilitate a balanced discussion among the participating members of the application having regard to the preliminary review and/or the presentation by the principal investigator (or his delegate).

5.3.2 All REC members shall make a declaration of conflict of interest (Attachment 7.2). A member who has declared a conflict of interest in an application shall neither take part in the discussion of nor vote on that application. Subject to the discretion of the person chairing the meeting, the member may be requested to withdraw from the meeting when that application is being considered and decided

5.4 Decisions and Notification

5.4.1 Only members who have participated in the review and discussion of an application may vote on that application.

5.4.2 The Chairman, Deputy Chairman or Acting Chairman shall endeavour to achieve a consensus among members. If consensus cannot be reached on the application,

the application shall be put to a vote. The application is approved if it is approved by the majority of the members who have participated in the review and discussion.

- 5.4.3 If the application is NOT APPROVED, the principal investigator will be informed in writing of the reasons for disapproval and the option to submit a new protocol (after amendment, modification or supplement of the original protocol) for consideration. The protocol will be returned to the principal investigator.
- 5.4.4 The meeting may, instead of putting the application to a vote, postpone decision on the application and request the principal investigator to respond to the objections raised by members within a specified period. After expiry of the specified period, the meeting may then reconvene to decide on the application, having regard to the investigator's response, if any.
- 5.4.5 The REC will issue to the principal investigator a Written Notification (Attachment 7.3) of its decision to approve / not approve the application, setting out the documents reviewed by the REC.
- 5.4.6 The decisions of the REC will be included in the Research Proposal File maintained by the REC Secretary. A letter of REC Review which documents the query or comment of the REC will be sent to the principal investigator.

6 Record

Not Applicable

7 Attachment

- 7.1 Response Form
- 7.2 Conflict of Interest Declaration Form
- 7.3 Written Notification

8 Reference Documents

- 8.1 Research Ethics Committee. *Standard Operating Procedure for Recruitment of Independent Consultants or Contractors for Research*. (A.2.3.6.2-RESEC-RESEC-H-PC)

Attachment 7.1

Response Form

HKSH Medical Group Research Ethics Committee
Response Form

Date: _____

RE: Title: _____

We would be grateful to receive your advice on this proposed research study protocol. Please kindly fax the reply slip below to The HKSH Medical Group.

Thank you for your kind attention.

Research Ethics Committee

To: HKSH Medical Group (Fax. No. 2892 7557 (Attn: Secretary))

Please tick '✓' the appropriate boxes:

☐ I endorse the proposed Research Study Protocol.

☐ I have the following queries / comments: (Please specify)

Name: _____ Signature: _____ Date: _____

Attachment 7.2
Conflict of Interest Declaration Form

HKSH Medical Group Research Ethics Committee

**Research Ethics Committee Member's
Conflict of Interest Declaration Form**

Study title

Please tick '✓' the appropriate boxes:

- ☐ I am not involved in, and have no conflicting interest (includes participating in or supervising the project, a financial interest, a personal or fiduciary relationship, or some other situation giving rise to a conflicting interest) in the research reviewed.
- ☐ I declare the following conditions concerning me and my immediate family members, which could cause conflict of interest.

Signed: _____

Date: _____

Name: _____

Attachment 7.3 (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 7.3 (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 _____
(Principal Investigator) HKSH Medical Group
(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 REC Chairperson/Designee	_____ Signature	_____ Date
---	--------------------	---------------



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HKSH Medical Group

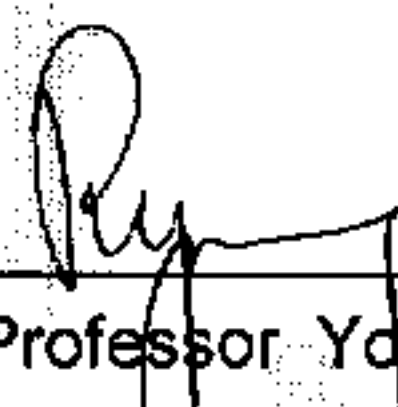
Standard Operating Procedure for Complaint Management for Research Ethics Committee

Revision Summary of the Last Revision

Version	Revision Details	Relevant Section	Effective Date
01	Initial release	N/A	17 July 2018
02	Revised format	Whole document	8 October 2019

Document Locations and Distribution if any

Controlled Soft Copy	Policy Portal in HKSH Medical Group
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 Professor Young Tse Tse, Rosie
 Chairman, Research Ethics Committee
 HKSH Medical Group
 8 October 2019

Prepared by : Research Ethics Committee Members
 Approved by Chairman : 08/10/2019
 First Issued : 17/07/2018
 Last Revised : N/A
 Reviewed : Refer to Content Page
 Risk Rating : N/A

Standard Operating Procedure for Complaint Management for Research Ethics Committee

1 Objective

The HKSH Medical Group (“the Group”) has a specific Policy on Complaint Management (A.6.1-HMC-MAT-H-PL), covering all types of complaint management processes within the Group. Complaints relating to Research Studies reviewed by REC also follow the Policy.

2 Scope and Definition

2.1 Same as Policy on Complaint Management (A.6.1-HMC-MAT-H-PL).

3 Responsibility

3.1 Same as Policy on Complaint Management (A.6.1-HMC-MAT-H-PL).

4 Training and Qualification

Not Applicable

5 Policy Details

5.1 Same as Policy on Complaint Management (A.6.1-HMC-MAT-H-PL).

6 Record

6.1 Same as Policy on Complaint Management (A.6.1-HMC-MAT-H-PL).

7 Attachment

7.1 Same as Policy on Complaint Management (A.6.1-HMC-MAT-H-PL).

8 Reference Documents

8.1 Hospital Administration and Nursing Administration. *Policy on Complaint Management.*
(A.6.1-HMC-MAT-H-PL)



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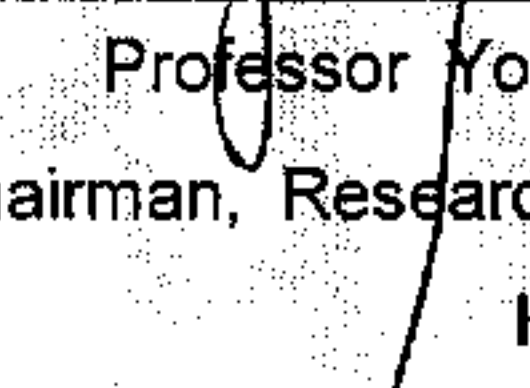
Standard Operating Procedure for Records Management for Research Ethics Committee

Revision Summary of the Last Revision

Version	Revision Details	Relevant Section	Effective Date
01	Initial release	N/A	17 July 2018
02	Restructure of the contents in REC SOP, to keep consistency between operation and REC SOP	Whole document	11 April 2019
03	Revised format	Whole document	8 October 2019

Document Locations and Distribution if any

Controlled Soft Copy	Policy Portal in HKSH Medical Group
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 Professor Young Tse Tse, Rosie
 Chairman, Research Ethics Committee
 HKSH Medical Group
 8 October 2019

Prepared by : Research Ethics Committee Members
 Approved by Chairman : 08/10/2019
 First Issued : 17/07/2018
 Last Revised : 11/04/2019
 Reviewed : Refer to Content Page
 Risk Rating : N/A

Standard Operating Procedure for Records Management for Research Ethics Committee

1 Objective

This Standard Operating Procedure (SOP) sets out the requirements for maintaining and preserving the records of the Research Ethics Committee (REC) of the HKSH Medical Group.

2 Scope and Definition

This SOP is applicable to the documentation of REC's SOPs, meetings, decisions, and research study applications.

3 Responsibility

The REC Secretary is responsible for the documentation of REC's SOPs, meetings, decisions and research study applications.

4 Training and Qualification

Not Applicable

5 Procedure Details (Maintenance of Records)

5.1 Electronic Database

5.1.1 An electronic database for all research study applications submitted to the REC for review shall be established and maintained by the REC Secretary.

5.1.2 The database should contain information about all research study applications (including approved, disapproved, ongoing, completed, and prematurely terminated studies), including but not limited to:

- (a) REC reference numbers;
- (b) Names and departments of principal investigators;
- (c) Application identifiers (e.g. study titles);
- (d) Dates of initial submission;
- (e) Dates of approval / disapproval;
- (f) Dates of study completion;
- (g) Dates of last progress report submission;
- (h) Current status of the study.

5.1.3 The REC Secretary is responsible for maintaining the database and supplying data therein to any governing body(ies) when necessary.

5.2 Records Retention

5.2.1 The REC Secretary shall retain all necessary documents and records relating to research studies, including but not limited to:

- (a) documents and records relating to initial review of the studies (e.g. initial Research Study Application Forms, study documents submitted by the investigators, review meeting agendas and minutes, list of reviewers and their conflict of interest declarations, relevant correspondences between the REC and investigators, and REC written decision(s)/opinion(s));
- (b) documents and records relating to continuous oversight of the studies (e.g. records for review of amendments/additional information, new information or deviations/compliance incidents, progress reports and relating publications); and
- (c) documents and records of study audits.

5.2.2 All records related to research study applications will be retained for at least 7 years after the completion, discontinuation, termination or withdrawal of the studies.

5.3 Confidentiality and security

5.3.1 The REC secretary shall sign the statement of confidentiality before discharging duties.

5.3.2 All documents must be stored in cabinet with lock inside REC secretariat with restricted access. All documents can only be accessed by the REC Secretary.

5.3.3 Electronic Database can be only accessed by the REC secretary with password protected personal account.

6 Record

Not Applicable

7 Attachment

Not Applicable

8 Reference Documents

Not Applicable