Research Ethics Committee
Standards of Operation Procedures

Revision Summary of the Last Revision

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Details</th>
<th>Relevant Section</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Initial release</td>
<td>N/A</td>
<td>01 September 2005</td>
</tr>
<tr>
<td>08</td>
<td>Review procedure Updated, Details of expedited review added</td>
<td>Section 3.2, Section 5</td>
<td>08 August 2017</td>
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<tr>
<td>09</td>
<td>Review of REC composition, training, declaration, review procedure, record retention, forms</td>
<td>Section 3.1, Section 3.1.3-3.1.5, Section 5.1.4, Section 5.2, Section 5.3.3, Attachments</td>
<td>17 July 2018</td>
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</table>

Document Locations and Distribution if any

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Prepared by: Research Ethics Committee
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Risk Rating: N/A

Professor Young Tse Tse, Rosie
Chairman, Research Ethics Committee
HKSH Medical Group
17 July 2018
Research Ethics Committee - Standards of Operation Procedures

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

2. Scope and Definition
2.2.1 The Medical Group REC will review and monitor all proposals for
   - Clinical trials and other clinical research studies.

2.2.2 Terms of Reference
   A. To review an 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 (GCP), 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.
   *The term "Investigator" is used throughout this SOP, it replaces the term "Principal Investigator"*

3. Responsibility
3.1 Composition of the REC
   3.1.1 The Committee consists of at least 5 members for a review meeting, who collectively have the qualifications and experience to review and evaluate the science, medical aspects, and ethics of the proposed trial / clinical research studies (Please refer to Membership formation for Research Ethics Committee for details).

   3.1.2 Research Committee (RC) is the screening tool of the Research Ethics Committee. Research Committee is to screen all the research proposals in The Medical Group (details refer to Attachment 7.4). Approval (Attachment 7.6) may be given by the Research Committee if no ethical issues are involved. Otherwise it will be referred to the Research Ethics Committee (REC). Any study involving human subjects, especially vulnerable subjects, will come under the ambit of the Research Ethics Committee.

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3.1.3 All members and secretaries of the REC should attend the Good Clinical Practice (GCP) training and REC Standard Operating Procedures (SOP) training delivered by the Clinical Trials Centre of The Medical Group before discharging the REC duties. Subsequent updates of the REC SOP will be sent to all members for information. All members and secretaries are required to sign the corresponding training record after completion of the training.

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

3.1.5 Secretaries of the REC should be given an independent workplace as office with the necessary accessories for the routine work. Access control of the workplace is required.

3.2 Functions of REC

3.2.1 Reviews of applications for research proposals by the Committee will be completed throughout the year on a meeting basis. The Committee will meet at least once a year.

3.2.2 The presence of a simple majority (50% of the membership) will constitute a quorum. The Committee will make its decisions at announced meetings at which at least a quorum is present. Only members who participate in the REC review and discussion will vote. Only members who are independent of the investigator(s) and sponsor of the clinical trial/clinical research studies will vote/provide opinion on clinical trial/clinical research studies related matters.

3.2.3 All communications and/or correspondence from Hospital investigators relating to submissions are to be channeled via the Secretariat, and under no circumstances should such investigators lobby or otherwise discuss decisions with any member of the Committee, unless the investigators are approached by the Chairman on behalf of the Committee.

3.2.4 The Chairman is responsible for chairing the meeting, conducting business so that each research proposal/ethical issue is fairly and completely reviewed, seeing that the Committee reaches a decision on the disposition of each research proposal/ethical issue and communicating these decisions to the Investigator/relevant person(s).

3.2.5 In the case of dissension between members, and assuming that such dissension cannot be resolved by the Chairman, the final decision of the Committee will then be made on a majority basis. At the discretion of the Chairman, the views of a dissenting member(s) can be appropriately recorded and/or publicized in such split
decisions.

3.2.6 Minutes of the meetings are to be reviewed and approved by the Chairman.

3.2.7 The Committee will submit an annual report of the work undertaken to the Hospital Management.

4. Training and Qualification

4.1 All the members of REC, once appointed, should attend the Good Clinical Practice (GCP) training and REC SOPs training before carried out the REC duties.

5. Procedure Details

5.1 Procedure: Application for a clinical trial / clinical research study

5.1.1 The Committee will review applications for clinical trials/clinical research studies to be conducted in The Medical Group.

5.1.2 The investigator should submit:

(a) 8 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

(b) 1 set of Investigator's 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) A copy of Clinical Trial Certificate issued by Department of Health.

5.1.3 Reviews of applications by the Committee will be completed throughout the year by holding regular review meetings at a frequency as the REC determines and ad hoc review meeting as the REC deems necessary. The Chairman or Vice/Deputy Chairman may, as he/she deems beneficial to the review of an application/submission, request a principal investigator (or his/her delegate) to participate and/or present the application/submission in a review meeting.

5.1.4 The Committee shall review the research proposal according to the SOP of Review of Research Application by Research Ethics Committee

5.1.5 For the application to be approved by a Committee meeting, it must be approved by all the members of the Committee. If the majority of the members do not approve,
the protocol will be returned to the Investigator as Not Approved, in which case a new
application will be required for resubmission. If a minority rejects the protocol, the
Investigator can respond to the objections raised and the Committee will review the
protocol a second time. After the second review, if at least one member still does not
approve, a meeting will be convened where the protocol will be approved or not
approved on a majority basis, with tied votes being not approved.

5.1.6 The final decisions of the Committee will be included in the Research Proposal File
maintained by the Secretariat. The Committee will review a clinical trial / clinical
research studies within 30 working days, discounting waiting time for further
information. A letter of REC Review which documents the query or comment of the
Committee will be sent to the principal investigator. The Committee will provide a
written notification (Attachment 7.2) to the Investigator of its decision to approve, not
approve or modify a research proposal with a record of documents reviewed by REC.
If a research proposal is disapproved, reasons for such disapproval will be specified to
the Investigator.

5.1.7 In the event of a disapproval, the Investigator will be informed that he has the following
options:
   (a) Resubmit a new protocol for the Committee's consideration.
   (b) Appeal in writing, stating his reason(s) for his appeal. His case will then be
       considered by the Committee in the next meeting.

5.1.8 Any amendments to the Protocol and/or Informed Consent must be submitted to the
Research Ethics Committee 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 track
changes.

5.2 Procedure: Review of continuing/completed clinical trials / clinical research studies

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

5.2.2 The Investigator is required to submit a progress report to the Committee using the
Study progress/Final 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 secretariat will send the Study progress/Final Report
form to the Investigators a month before due date of each study.

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

5.2.3 The major way of REC in performing review is by holding Committee meetings. However, the REC chairman or the appointed member(s) of REC will consider conducting an expedited review for the following scenarios:

1) Minor amendments without affecting the subjects’ risk to benefit ratio of participating in the trial / clinical research study.
2) Trial(s) / study(ies) with no recruited subject for the time being;
3) Trial(s) / study(ies) with all interventional procedures completed;
4) The expected Serious Adverse Event (SAE)

For 1), Based on the results of the review, the Committee will provide a written reply to the investigator, with conditional clause(s) for protocol compliance and/or reporting at a shorter interval for observation when deem necessary.

For 2) – 5), a written reply from the Committee will be given to the investigator after the expedited review is completed.

Expedited review is responsible by one or two committee member(s). The result(s) of the expedited review will be notified in the next REC meeting. Under the following scenarios, the expedited review will be turned into a full review.

1) The opinion from the expedited review is negative.
2) The opinions from two committee members are inconsistent.
3) Member(s) of the REC deemed it necessary for a full review.

5.2.4 The Investigator should promptly report 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 serious adverse events (SAEs) and safety updates. This information will be reviewed by all the members of the Committee.
(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.

5.2.5 The Chairman or a Vice/Deputy Chairman (or designee) will perform a review on any
scenarios in 5.2.4 and the reports in 5.2.2. Should there be any rectification/remedial/modification action(s) listed in 5.2.6 below, the Committee will notify Principal Investigator in writing within fourteen (14) calendar days after the decision is made. In case there is no concern or comment on the new information, an acknowledgement of receipt of the submission will be issued to the principal investigator.

5.2.6 Rectification/Remedial/Modification Actions: The REC will have the right to:
(a) Request the Principal investigator to take appropriate rectification, remedial and/or modification action(s) with respect to the deviation/incident;
(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.

5.3 Documentation
5.3.1 The REC Secretariat will maintain and retain the following records:
(a) Written procedures
(b) Membership lists & CVs of member
(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

5.3.2 Written procedures and membership lists will be made available to the Hospital Management Committee, Investigators or Sponsors and authorized personnel of the Government.

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

5.4 Eligibility of investigators
The Committee will consider the qualifications of the proposed trial, as documented by a
current curriculum vitae and/or by any other relevant documentation the REC requests.

5.5 Informed Consent

5.5.1 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 / study Subjects are described in detail of the Guideline for Good Clinical Practice. The investigator is required to complete the “Consent Form Checklist” section of Form A: Research Study Application Form, when submitting the protocol for REC approval.

5.5.2 The REC will review both the amount and method of payment to subjects to assure 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 should be included in the written consent form and any other written information to be provided to subjects.

5.6 Review and revisions

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

5.7 Abbreviations

REC = Research Ethics Committee
GCP = Good Clinical Practice
SAE = Serious Adverse Event
SOP = Standard Operating Procedure

5.8 Definitions

**Adverse Event:** An adverse event is any untoward medical occurrence in a patient or clinical investigation subject 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 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 the Guidelines for 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, Good Clinical Practice (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 all investigational product(s), and/or to study 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 Medical Group to provide regulatory affairs support and monitoring role of the research studies in The Medical Group. It is responsible for CFDA centre accreditation for research.

**Good Clinical Practice**: A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the rights, integrity, and confidentiality of trial subjects are protected.

**Research Ethics Committee**: An independent body (a review board or a committee, institutional, regional, national or supranational), constituted of medical/scientific professionals and non-medical/non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favourable opinion on the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

**Research Committee**: A sub-committee of REC to screen all the research proposals in the hospital. The RC plays a vital part in ensuring that the research done at The Medical Group is of the highest scientific standards, and that the safety and welfare of the people who participate in the research are protected.

**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 is 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 ally other bodies having the power to regulate.

**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
- 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 (SOP):** 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.

6. Record

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<th>Record</th>
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<td>1.</td>
<td>Form A – Research Study Application Form</td>
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<td>2.</td>
<td>Written Notification</td>
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<td>Investigator</td>
</tr>
<tr>
<td>3.</td>
<td>Research Study Progress Report Form</td>
<td>Indefinite</td>
<td>Secretariat</td>
</tr>
<tr>
<td>4.</td>
<td>Research Study Approval Form</td>
<td>Indefinite</td>
<td>Secretariat</td>
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<tr>
<td>5.</td>
<td>Research Committee Approval Letter</td>
<td>Indefinite</td>
<td>Investigator</td>
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</table>

7. Attachment

7.1 Form A – Research Study Application Form
7.2 Written Notification
7.3 Research Study Progress Report Form
7.4 Application Process
7.5 Research Study Approval Form
7.6 Research Committee Approval Letter

8. Reference Documents

Not Applicable
PART I: Study Description

1. Title of Study

2. Principal Investigator

<table>
<thead>
<tr>
<th>Name</th>
<th>Designation</th>
<th>Department/Division</th>
</tr>
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<tbody>
<tr>
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</table>

*Please attach curriculum vitae*

3. Co-investigators

<table>
<thead>
<tr>
<th>Name</th>
<th>Designation</th>
<th>Department/Division</th>
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</table>

*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? □ Yes □ No

If so, please specify which unit/institution:

5.2

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


7. Aim of the Study and Expected Outcome


8. Study Design & Methodology

8.1 Non-experimental / Observational study  (omit PART II. Experimental study)
- Prospective, observational study
- Retrospective, chart review study
- Other, specify: ______________________

8.2 Prospective, Experimental Study
- Randomized controlled trial
- Non-randomized controlled trial
- Uncontrolled trial
- Other, specify: ______________________

9. Research Plan and Methodology

*Attach the research protocol instead, if available*
10. Study Subjects

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<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>10.1</td>
<td>How many subjects will be recruited locally? Explain rationale for sample size calculation if possible.</td>
</tr>
<tr>
<td>10.2</td>
<td>How will subjects (patients/controls) be identified and recruited?</td>
</tr>
<tr>
<td>10.3</td>
<td>What are the inclusion and exclusion criteria?</td>
</tr>
<tr>
<td>10.4</td>
<td>If randomization is used, explain the process:</td>
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</table>
## PART II: EXPERIMENTAL STUDY

(to be completed for Experimental Study only)

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<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
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<tbody>
<tr>
<td>11.1 Will any product be administered to subjects for the purpose of this study? i.e. in addition to treatment the subjects would receive if not participating in research</td>
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<tr>
<td>Go to Q 13.2 if “no”, specify if “yes” Drug. The drug trial is</td>
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<tr>
<td>Phase</td>
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<tr>
<td>Medical device</td>
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<tr>
<td>Others</td>
<td></td>
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<tr>
<td>11.2 Is this study sponsored by industry/commercial agency?</td>
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<tr>
<td>If yes, specify nature of sponsorship:</td>
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<tr>
<td>11.3 Is the product licensed in Hong Kong?</td>
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<tr>
<td>11.4 Is the product licensed in other countries?</td>
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<td>If yes, specify where:</td>
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<tr>
<td>11.5 Is the product being studied for licensed indications?</td>
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<tr>
<td>11.6 Has the procedure been undertaken before elsewhere?</td>
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<tr>
<td>If yes, please give short description:</td>
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<tr>
<td>11.7 Is there a plan to apply for a clinical trials certificate?</td>
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</table>
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?  □ Yes  □ No

13.2 Will the subjects receive payment or other benefits?  □ Yes  □ No

If yes, specify nature and amount:

14. Indemnity and Compensation

14.1 Is there an external indemnity/insurance provided?  □ Yes  □ No

14.2 Is the indemnity supported by an insurance policy?  □ Yes  □ No

14.3 If yes, is an insurance certificate available for review?  □ Yes  □ No
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

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

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?

<table>
<thead>
<tr>
<th>Type of Assistance</th>
<th>Specify</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statistical support</td>
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<tr>
<td>Clerical</td>
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<td>I.T.</td>
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<tr>
<td>Financial support</td>
<td>□</td>
</tr>
<tr>
<td>Other</td>
<td>□</td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Co-investigators:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix A: INFORMED CONSENT CHECKLIST

Please indicate where the following items may be found.

<table>
<thead>
<tr>
<th>Patient Information Sheet</th>
<th>Consent Form</th>
<th>Not Included</th>
</tr>
</thead>
<tbody>
<tr>
<td>That the trial involves research and those aspects of the trial that are experimental</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The purpose of the trial</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The trial treatment(s) and the probability for random assignment to each treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The subject’s responsibilities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The trial procedures to be followed, including all invasive procedures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The reasonably foreseeable risks or inconveniences to the subject and when applicable, to an embryo, foetus, or nursing infant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The compensation and/or treatment available to the subject in the event of trial-related injury</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The anticipated pro-rated payment, if any, to the subject for participating in the trial</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The anticipated expenses, if any, to the subject for participating in the trial</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information Sheet</td>
<td>Consent Form</td>
<td>Not Included</td>
</tr>
<tr>
<td>-------------------</td>
<td>--------------</td>
<td>-------------</td>
</tr>
<tr>
<td>That records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and regulations, will not be made publicly available. If the results of the trial are published, the subject’s identity will remain confidential.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The foreseeable circumstances and/or reasons under which the subject’s participation in the trial may be terminated.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The expected duration of the subject’s participation in the trial.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The approximate number of subjects involved in the trial.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>That the investigator includes the statement “The institution will receive payment to cover the administrative costs and trial related expense” or similar.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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 in principle/ not approved for the application of 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 secretariat 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
RESEARCH ETHICS COMMITTEE OF THE HKSH MEDICAL GROUP

APPROVAL FORM

The ________________________________
(Name of Research Ethics Committee)

voted at its meeting on ______________ to give FINAL 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: ___________ Date: ___________
Consent Form in Chinese Version: ___________ Date: ___________
Investigator Brochure 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 ________________________________
REG Chairperson/Designee

Signature ________________________________

Date ________________________________

Research Ethics Committee – Standards of Operation Procedures
HKSH V09 / 17 July 2018
# RESEARCH STUDY PROGRESS REPORT FORM

## PART I: Research Identification

<table>
<thead>
<tr>
<th>Title of Study</th>
<th>Protocol no.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Principal Investigator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Start Date</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

## PART II: Progress Report

<table>
<thead>
<tr>
<th>Report period</th>
<th>Planned sample size (local)</th>
<th>No. recruited</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No. completed study</th>
<th>No. withdrew</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Withdrawal reasons:

## PART III: Changes on Protocol

<table>
<thead>
<tr>
<th>Study protocol change</th>
<th>Investigator change</th>
<th>Have they been reported?</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

(If no, please attach application for the change)

## PART IV: Summary of Serious Adverse Events

<table>
<thead>
<tr>
<th>Is there any Serious Adverse Event of the study?</th>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Does the Serious Adverse Event affect the study?

<table>
<thead>
<tr>
<th>No</th>
<th>Yes, please specify</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

RESECC002 H&E-03-092017

Research Study Progress Report Form

Page 1 of 2

Research Ethics Committee – Standards of Operation Procedures
HKSH V09 / 17 July 2018

Page 23 of 29
### PART V: Summary of Complaints from Subjects

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is there any complaint from the subjects?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### PART VI: Updated Information

<table>
<thead>
<tr>
<th>Question</th>
<th>No</th>
<th>Yes</th>
<th>Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the Certificate of Insurance of the study still valid? Please attach renewed if the present one is expired.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### PART VII: Current Progress of Study

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continue according to the plan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extend study period</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Premature termination</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ended according to the plan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical Improvement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plan for publication and/or conference presentation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study was published</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Remarks:

*Please attach a copy of publication when available*

Report by:

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

RESEC.002-H8E-092017

Page 2 of 2

Research Study Progress Report Form

香港聖保羅藥局成員 A member of HKSH Medical Group
(1) Research Study Application Form

- This form is to be completed by the Principal Investigator (PI) of the study.
- Any documents, certificates related to the study should be attached to the application form upon submission. Some important documents to include in the ‘Research Application Package’:
  - Study Protocol
  - Patient Informed Consent Forms (English and Chinese versions)
  - Curriculum Vita of all Investigators involved in the study
  - Case report forms used for data collection

The following documents are required if applicable:
  - Doctors’ consent forms
  - Documents on study indemnity, insurance
  - Clinical Trial certificate

(2) Submission to the Secretary of The Medical Group Research Committee

- The Application package (including relevant documents stated above) should be submitted to the RC Secretary for processing.
- The secretary will screen for the following:
  - The application form is appropriately filled out
  - Signatures from all the investigators are collected
  - All relevant documents are attached
  - Contents in the application form corresponds to that in the protocol
  - The application form and other documents provide details to the study and that could be understood by a lay person
- If amendments to the Application form and protocol are required, the secretary is responsible for contacting the PI to request these changes

(3) Preliminary Review by the RC Chairman and Vice-chairman

- When the application package fulfills the above criteria upon initial screening, it will be forwarded to the Chairman and Vice-chairman for preliminary review.
A 'Research Study Approval Form (Attachment 7.5)' will be attached to the front of the package.

The Chairman and Vice-chairman will perform preliminary review. They will:

i. thoroughly review the application package and note down their concerns and queries about the study on the Approval Form.

ii. decide whether the Research study is experimental in nature or involves human subjects and require the approval of the REC.

iii. return the Study Approval Form to the Secretary. The application package may be retained for future reference.

iv. instruct the secretary what actions to be taken. The following are some common actions to be taken after preliminary review:
   - Accept or reject the application
   - For accepted application,
     - forward the application to the REC if ethical issues involved (step 4a)
     - Circulate the application package to other RC members for review and approval if no ethical issues involved (step 4b)

(4a) Forward application to the Research Ethics Committee

The Secretary will:

- Communicate with the REC secretary and make arrangements in the transfer of the application. The application will be processed according to the SOP of Review of Research Application by Research Ethics Committee
- Forward a copy of the application package to the CTC while retaining a copy for record.

(4b) Circulate the application package to Research Committee Members for review

The package should include the following:

- Research Study Approval Form
  - this form should be returned to the Secretary after 3 weeks
  - members will be reminded to return the form at the end of 2 weeks.
- Full Research Application package including the application form

Committee members may retain the application package for future reference.

(5) Collection of Feedback from RC Chairman, Vice-chairman and Members

The Secretary should ensure the following:

- All RC members has reviewed the application package and returned the form within the set time limit
• From the forms, consolidate all queries, comments and suggested actions to be taken
• If no queries/comments are raised, skip step 6 to step 7

(6) Send feedback from RC Chairman, Vice-chairman and Members to the PI

The Secretary should:
• Ask for PI’s response to the anonymous queries from committee
• Follow up on whether all suggested actions have been taken

If no significant concerns are further raised → step (7)
If there are significant concerns still to be resolved, the set of Queries and PI’s feedback should be forwarded to Chairman and Vice-chairman for further review and a RC meeting may be arranged for a face-to-face interview with the PI if necessary.

(7) Final review by the Chairman
• They will decide whether the research study now meets the standards of The Medical Group.

(8) Approval by the RC
• If standards are met a formal letter of approval signed by the RC Chairman will be issued to the PI.
• The PI may now commence the study at The Medical Group.
HKSH Medical Group Research Committee

Attachment 7.5
Research Study Approval Form

Research Study Approval Form

Study Title:

Principal Investigator: ___________________________ Department: ___________________________

To: Committee Members

Please kindly tick the appropriate box(es) below, sign. Thank you very much.

☐ I approve the proposed Research Study Protocol

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

<table>
<thead>
<tr>
<th>No.</th>
<th>Queries/Comments</th>
<th>Actions to be taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Name: ___________________________ Signature: ___________________________ Date: ___________________________
Investigator’s Address

Date

Dear Investigator,

RE: Research Study Application

Thank you for your research application.

I am pleased to inform you that the HKSH Medical Group Research Committee has given your research team approval on the following research project:

Study Title

Please forward to the Research Committee a copy of an interim report at 6 months, or a final report of the project whichever comes sooner.

If the study will be published, please also provide information on its publication.

Yours Sincerely,

Chairman, Research Committee

Please quote RC Ref. No: _______________ in future correspondence with the Committee
Standard Operating Procedure for Membership Formation for Research Ethics Committee

Revision Summary of the Last Revision

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Details</th>
<th>Relevant Section</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Initial release</td>
<td>N/A</td>
<td>17 July 2018</td>
</tr>
</tbody>
</table>

Document Locations and Distribution if any

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

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

Professor Young Tse Tse, Rosle
Chairman, Research Ethics Committee
HKSH Medical Group
17 July 2018
Membership Formation for Research Ethics Committee

1 Objective
This Standard Operating Procedure (SOP) describes the process and procedure for forming and managing a Research Ethics Committee (REC) in the HKSH Medical Group (The Medical Group). According to China GCP, the REC should consist of at least 5 members from each of the categories - medical / pharmaceutical professionals, non-medical / pharmaceutical professionals, legal experts, members of different genders and independent members who are not related to Research / Clinical Trials Unit.

2 Scope and Definition
The Medical Group REC will review and monitor all proposals for
- Clinical trials and other clinical research studies.

3 Responsibility
3.1 To review an 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.

3.2 To evaluate safety of the ongoing clinical trials / clinical research studies based on reports from sponsors and investigators.

3.3 To ensure that all the ongoing clinical trials / clinical research studies are carried out in accordance with the Guideline for Good Clinical Practice (GCP), the Declaration of Helsinki of the World Medical Association (Declaration of Helsinki), the US Code of Federal Regulations (if applicable) and with the applicable regulatory requirements.

3.4 To note any change of protocols or termination of clinical trials / clinical research studies.
*The term "Investigator" is used throughout this SOP, it replaces the term "Principal Investigator".

4 Training and Qualification
4.1 All the members of REC, once appointed, should attend the Good Clinical Practice (GCP) training and REC SOPs training before carried out the REC duties.

5 Procedure Details
5.1 Composition of the REC
5.1.1 The Committee should consists of at least 5 members from each of the categories from 5.1.2.1 to 5.1.2.5 below in order to hold for a research ethics review meeting, who collectively have the qualifications and experience to review and evaluate the science, medical aspects and ethics of the proposed trial / clinical research study.

5.1.2 Committee members are invited and appointed by the Group Management
Committee of The Medical Group. Members are selected on the basis of maturity, experience and expertise.

Other applicable selection criteria for the Committee:
5.1.2.1 At least two members from medical / pharmaceutical field
5.1.2.2 At least two members from non-medical/ pharmaceutical field
5.1.2.3 At least two members from legal expertise
5.1.2.4 At least one member from each gender
5.1.2.5 At least two members who are independent of research/clinical trials unit
5.1.2.6 Only those IRB/REC members who are independent of the investigator and the sponsor of the trial / research study should vote/provide opinion on a trial or research study-related matter.

5.1.3 The Chairman and Deputy Chairman (male or female) of the Committee will be elected among members. When the Chairman is absent, an Acting Chairman will be appointed by the Chairman or elected among the members.

5.1.4 The Chairman shall nominate a suitable number of candidates with a suitable mix of backgrounds and expertise as members for supporting The Medical Group REC's responsibilities.

5.1.5 The term of chairmanship and membership will be three years. There is no restriction for reappointment as long as the Chairman / members continue to fulfill the relevant requirements.

5.1.6 In the event of resignation or death of a member, the Group Management Committee of The Medical Group will appoint a member to serve the unexpired portion of the resigning/deceased member's term.

5.1.7 The REC Secretariat is required to maintain an updated list of REC members and their qualifications. All the updated information of the REC members including their contact, membership list, occupation, organization as well as the work flow and all relevant SOPs of REC will be publicized to the general public through the website of the HKSH Medical Group.

5.1.8 Documentation
5.1.8.1 The REC Secretariat will maintain and retain the following records:
   (a) This SOP
   (b) Membership lists & CVs of member
   (c) Acceptance letter of membership of all REC members
6 Record
Not Applicable

7 Attachment
Not Applicable

8 Reference Documents
Not Applicable
Standard Operating Procedure for
Recruitment of Independent Consultant or Contractor for
Research Review for Research Ethics Committee

Revision Summary of the Last Revision

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Details</th>
<th>Relevant Section</th>
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<td>N/A</td>
<td>17 July 2018</td>
</tr>
</tbody>
</table>

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

Professor Young Tse Tse, Rosie
Chairman, Research Ethics Committee
HKSH Medical Group
17 July 2018

Prepared by: Research Ethics Committee Members
Approved by Chairman: 17/07/2018
First Issued: 17/07/2018
Revised: N/A
Reviewed: Refer to Content Page
Risk Rating: N/A
Recruitment of Independent Consultant or Contractor for Research Review for Research Ethics Committee

1 Objective
1.1 Readers should be able to understand the recruitment procedures of independent consultant for research review by Research Ethics Committee (REC).

2 Scope and Definition
2.1 According to 3.2.6 of ICH GCP, An IRB/IEC may invite non members with expertise in special areas for assistance. This SOP is applicable to the recruitment of independent consultant for research review by REC.

3 Responsibility
3.1 REC is responsible for the management of REC’s independent consultant / contractor for research.
3.2 For situations when remuneration to independent consultant/contractor is required for service delivery, REC should follow the HKSH Medical Group’s procedure for requisition for fixed asset / valuable items or purchase of service rendered by external contractors.
3.3 Supplies Department assists in sourcing relevant external suppliers/vendors, liaising between the external suppliers / internal users, preparing quotations and proceeding purchasing procedure.

4 Training and Qualification
Not Applicable

5 Procedure Details
5.1 Chairman of REC, after consensus is made among the members of REC for the requirements of acquiring the independent consultant / contractor, passes the details to the secretaries of the REC to follow up.

5.2 REC secretary fills in the Fixed Asset / Purchase of Service Rendered by External Contractors Requisition Form (Attachment 7.1) with the requirements and specifications of the service on the Requisition form and submit the Requisition Form to REC Chairman for signature and approval.

5.3 For the purchase/service amount HK$100,000 or above, the signed form will be submitted to Purchasing Committee for initial support before the purchasing procedure. Please refer to Attachment 7.2 – Workflow of Requisition for Fixed Asset and Valuable Items / Purchase of Service Rendered by External Contractors for details.
5.4 For total purchase of service amount less than HK$100,000, Department submits the Fixed Asset/ Purchase of Service Rendered by External Contractors requisition to Supplies Department for purchasing procedure and to Hospital Management Committee for final approval. Please refer to Attachment 7.3 – Workflow of Requisition for Fixed Asset / Purchase of Service Rendered by External Contractors (below HK$100,000).

5.5 Supplies Department will source the required service, undergo price negotiation, time of delivery and warranty services, if any, etc. After all, Supplies Department will forward final quotation to Department for its verification and acceptance by counter-signature into the stamp.

5.6 Supplies Department keeps the original copy of the final approved Fixed Asset / Purchase of Service Rendered by External Contractors Requisition Form, 1st copy and 2nd copy are sent to the REC secretarial office and Nursing Administration respectively for their record.

5.7 For new equipment or service with value of HK$10,000.00 or above, REC secretarial office is required to fill in “Application for Trial Use of New Equipment/Service (Attachment 7.4). Supplies Department will coordinate with REC secretarial office to arrange product/service demonstration and evaluation.

6 Record

<table>
<thead>
<tr>
<th>No.</th>
<th>Record</th>
<th>Retention Period</th>
<th>Retained by</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Fixed Asset / Purchase of Service Rendered by External Contractors Requisition Form</td>
<td>7 years</td>
<td>Supplies Department</td>
</tr>
<tr>
<td>2.</td>
<td>Application for Trial Use of New Equipment</td>
<td>7 years</td>
<td>Supplies Department</td>
</tr>
</tbody>
</table>

7 Attachment

7.1 Fixed Asset / Purchase of Service Rendered by External Contractors Requisition Form (refer to Attachment 7.1)

7.2 Workflow of Requisition for Fixed Asset and Valuable Items / Purchase of Service Rendered by External Contractors

7.3 Workflow of Requisition for Fixed Asset / Purchase of Service Rendered by External Contractors (below HK$100,000)

7.4 Application for Trial Use of New Equipment/Service

8 Reference Documents

8.1 Independent contractor agreement: Sample template
https://www.marsdd.com/mars-library/independent-contractor-agreement-sample-template/
Fixed Asset / Purchase of Service Rendered by External Contractors Requisition Form

Sample

Department: __________________________
Ext: __________________________
Fax: __________________________
Requested Item: __________________________

Quantity: __________________________
Description & Specification: __________________________

Existing Stock: __________________________
Reasons: __________________________

Suggested Sources: (Quote received if available), camatan packet or equivalent

1st Choice: __________________________
Model: __________________________
Price: __________________________
Supplier: __________________________

2nd Choice: __________________________
Model: __________________________
Price: __________________________
Supplier: __________________________

3rd Choice: __________________________
Model: __________________________
Price: __________________________
Supplier: __________________________

Reasons for selecting the specified models: __________________________

Department Supervisor: __________________________
Date: __________________________

Department Head: __________________________
Date: __________________________

SOP for Recruitment of Independent Consultant or Contractor for Research Review for Research Ethics Committee
HKSH V01 / 17 July 2018
Attachment 7.2 (P.1/2)
Workflow of Requisition for Fixed Asset and Valuable Items / Purchase of Service Rendered by External Contractors
Workflow of Requisition for Fixed Asset and Valuable Items / Purchase of Service Rendered by External Contractors

1. Department Requisition for Fixed Asset and Valuable Items / Purchase of Service Rendered by External Contractors

2. Endorsed by Department Head / Nursing Admin.

3. Total Purchase Amount < HK$100,000
   - Supplies Department to proceed purchasing procedure
   - Refer to Attachment 7.3

4. Total Purchase Amount > HK$100,000
   - Supported by Purchasing Committee
     - For special items requiring exception
       - Audit Committee endorsement
       - Supplies Department to prepare quotation from vendor
     - Requested items and quotations recommended by Purchasing Committee
       - Endorsed by Hospital Management Committee

9. Final endorsed requisition passed to Hospital Board

10. Supplies Department to proceed purchasing procedure
固定資産 (Fixed Assets) 申請指引 (十萬元以下)

- 申請部門須填寫一式三份的固定資産申請表
- 請說明所需產品的要求及規格
- 如有建議品牌及型號，請在申請表上註明
- 領長後請交部門主任及本院主任醫生簽署，查核

交物料供應部處理

物料供應部會接獲相關建議，與供應商商討價錢、交貨期、售後保養、維修服務等
報價單將會交由申請部門核簽確認最終產品型號及配件。
(報價單上會蓋上附件 7.3 之標本印章供部門簽署)

物料供應部將同固定資産表及報價單呈交院長批核

物料供應部將保留複核完成後正本，第一副本交給
申請部門存檔，而第二副本交給護理行政部存檔

- Fixed Asset 定義：請參照附件 7.6
- 有關電腦硬件及軟件的固定資産表 (滑鼠、鍵盤，中文手寫板， 九方中文輸入法
軟件除外)，請直接交予資訊科技部
Sample

Hong Kong Sanatorium & Hospital
Record of Equipment Received from Supplies for Trial Use
(Unit Value $10,000 or above)

From: ____________________________
To: Manager (Administration)
   (Through Deputy Manager (Supplies))

APPLICATION FOR TRIAL USE OF NEW EQUIPMENT

I write to apply for endorsement to have the following equipment put on trial in the department:

Supplier & Product Information: (to be completed by supplier or attach supporting letter from supplier)

Supplier: ____________________________
Company Chop: _______________________
Signature: __________________________
Contact Person: ______________________
Telephone No.: _______________________
Date: __/__/____

Name and Model of Equipment


Unit Price: __________________________
Trial Period: ________________________

Manufacturer: ________________________
Country of Origin: ____________________

Comply with International Standard: □ FDA □ CE □ Japanese Standard

Reference site: Yes / No If yes, please specify: ____________________________

Requested By:
Name & signature of Dept. In-charge: ____________________________
Department: __________________________

Name of Doctor performed this trial: ____________________________
Date: __/__/____

Endorsed By:
Name: ____________________________
Supplies Department
Signature: __________________________
Date: __/__/____

NOTE: The Hospital has no obligation, commitment or liability to the supplier on the purchase or for the damage of the equipment.

Reference:
1. Certificate of Approval by a recognized official agency.
2. Copies of literature on the use of equipment.
Standard Operating Procedure for
Review of Research Application for Research Ethics Committee

Revision Summary of the Last Revision

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Prepared by: Research Ethics Committee
Approved by Chairman: 17/07/2018
First Issued: 17/07/2018
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Risk Rating: N/A

Professor Young Tse Tse, Rosie
Chairman, Research Ethics Committee
HKSH Medical Group
17 July 2018
Review of Research Application by Research Ethics Committee

1 Objective
1.1 Readers should be able to understand the definition and the standard flow of operation for review of research application by Research Ethics Committee (REC).

2 Scope and Definition
2.1 This SOP is applicable to the review of research application by REC.

3 Responsibility
3.1 The secretaries of REC are responsible for the management of REC’s review for the research application.

4 Training and Qualification
Not Applicable

5 Procedure Details
5.1 Type of Review
5.1.1 Full Review
Reviews of applications by the Committee will be completed throughout the year by holding regular review meetings at a frequency as the REC determines and ad hoc review meeting as the REC deems necessary.

5.1.2 Expedited Review
The major way of REC in performing review is by holding Committee meetings. However, the REC chairman or the appointed member(s) of REC will consider conducting an expedited review for the following scenarios:

i. Minor amendments without affecting the subjects’ risk to benefit ratio of participating in the trial / research study.

ii. Trial(s) / research study(ies) with no recruited subject for the time being;

iii. Trial(s) / research study(ies) with all interventional procedures completed;

iv. The expected Serious Adverse Event (SAE)

5.2 Review Procedure
5.2.1 Full Review Procedure
5.2.1.1 Meeting Schedule
Regular review meetings at a frequency as the REC determines will be scheduled by the Secretaries at the end of the previous year. Ad hoc review meetings will be held as the REC deems necessary. Applicant is required to submit the application at least 2 weeks before the scheduled meeting.
5.2.1.2 Quorum of Reviewers and other Attendees

1) The quorum for a full review meeting is constituted by a simple majority (50% of the membership) plus (2).

2) 1 member from each of the five categories, medical/pharmaceutical professional; non medical/pharmaceutical professional; legal expert; member of different genders; neither trial / research study involved nor trial / research study site staff.

3) Each review meeting will be chaired by the Chairman or a Vice/Deputy Chairman.

4) The Chairman or Vice/Deputy Chairman may, as he/she deems beneficial to the review of an application/submission, request a principal investigator (or his/her delegate) to participate and/or present the application/submission in a review meeting.

5) Guest members, who may be invited when deemed necessary. If the Committee does not have the necessary expertise to evaluate the scientific merit or moral issues of a research proposal, the Committee will obtain the expert opinion of a suitably qualified and informed external review.

5.2.1.3 Preliminary Review before Meeting

For each application the Secretariat will, prior to the review meeting, send the application documents to the reviewers at least 7 calendar days before the review meeting for performing preliminary review. The members may reach one of the following decisions regarding each research proposal by completing the Response Form (Attachment 7.1):

a) I endorse the proposed protocol
b) I have the following queries/comments

In case of b), the Investigator should resolve the queries/comments before the review meeting, or prepare materials to response in the meeting.

All members of the Research Ethics Committee shall make a declaration of having no conflict of interest (Attachment 7.2) or otherwise withdraw from the review.

5.2.1.4 Final Review in the Meeting

The Chairman or Vice/Deputy Chairman will use his/her endeavors to facilitate a balanced discussion among the participating reviewers on the application document, results of preliminary review and/or the presentation by the principal investigator (or his/her delegate).
5.2.1.5 Decisions and Notification

For the application to be approved by a Committee meeting, it must be approved by all the members of the Committee. If the majority of the members do not approve, the protocol will be returned to the Investigator as Not Approved, in which case a new application will be required for resubmission. If a minority rejects the protocol, the Investigator can respond to the objections raised and the Committee will review the protocol a second time. After the second review, if at least one member still does not approve, a meeting will be convened where the protocol will be approved or not approved on a majority basis, with tied votes being not approved. The Committee will provide a written notification to the Investigator of its decision to approve, not approve or modify a research proposal with a record of documents reviewed by REC. If a research proposal is disapproved, reasons for such disapproval will be specified to the Investigator.

5.2.2 Expedited Review Procedure

5.2.2.1 Expedited review is responsible by one or two committee member(s).

5.2.2.2 Secretaries will forward the application documents to the member(s) for review. The member(s) shall review the application documents by completing the Response Form (Attachment 7.1). Members of the REC shall make a declaration of having no conflict of interest (Attachment 7.2) or otherwise withdraw from the review. Uncomplicated reviews shall take 14-21 working days. The members may reach one of the following decisions regarding each research proposal:

a) I endorse the proposed protocol
b) I have the following queries/ comments
c) I proposed to hold a meeting of the Research Ethics Committee to consider this application

In case of b), the Investigator should resolve the queries raised within 7 days. The Investigator's response shall then be forwarded to all the members. The members who raised the queries will reconsider the investigator's response within 7 days.

5.2.2.3 The result(s) of the expedited review will be notified in the next REC meeting.

5.2.2.4 Under the following scenarios, the expedited review will be turned into a full review.

1) The opinion from the expedited review is negative.
2) The opinions from two committee members are inconsistent.
3) Member(s) of the REC deemed it necessary for a full review.

5.2.2.5 Notification of Decisions
For scenario i) stated in 5.1.2, the Committee will provide a written reply to the investigator based on the review results, with conditional clause(s) for protocol compliance and/or reporting at a shorter interval for observation when deem necessary.
For scenarios ii) – iv) stated in 5.1.2, a written reply from the Committee will be given to the investigator after the expedited review is completed.

6 Record
Not Applicable

7 Attachment
7.1 Response Form
7.2 Conflict of Interest Declaration Form

8 Reference Documents
Not Applicable
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 Medical Group.

Thank you for your kind attention.

--------------------------------------------------
Research Ethics Committee

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

Please tick ‘✓’ the appropriate boxes:

☐ I endorse the proposed protocol for the Research Study Protocol.
☐ I have the following queries / comments: (Please specify)

________________________________________________________________________
________________________________________________________________________

☐ I proposed to hold a meeting of the Research Ethics Committee to consider this application. (For expedited review.)

Name: ___________________________ Signature: ___________________________ Date: ___________________________
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: ___________________________
Standard Operating Procedure for
Complaint Management for Research Ethics Committee

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SOP for Complaint Management for Research Ethics Committee
HKSH V01 / 17 July 2018
Complaint Management for Research Ethics Committee

1 Objective
1.1 The HKSH Medical Group (The Medical Group) has a specific Policy on Complaint Management (A.6.1-GMC-MAT-H-PL), covering all types of complaint management processes within The Medical 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-GMC-MAT-H-PL).

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

4 Training and Qualification
Not Applicable

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

6 Record

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

8 Reference Documents
8.1 Same as Policy on Complaint Management (A.6.1-GMC-MAT-H-PL)
Standard Operating Procedure for
Records Management for Research Ethics Committee

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Risk Rating: N/A

Professor Young Tse Tse, Rosie
Chairman, Research Ethics Committee
HKSH Medical Group
17 July 2018
Records Management for Research Ethics Committee

1 Objective
1.1 Readers should be able to understand the definition and the standard flow of operation for documentation of Research Ethics Committee's SOP, meetings and application.

2 Scope and Definition
2.1 This SOP is applicable to the documentation of Research Ethics Committee's SOP, meetings and application.

3 Responsibility
3.1 The secretaries of Research Ethics Committee are responsible for the documentation of REC’s meetings and application.

4 Training and Qualification
Not Applicable

5 Policy Details
5.1 Electronic Database
5.1.1 An electronic database for the Research Application submitted to the REC for review was established and is being maintained by the REC secretaries. The database contains information about the Research Application (including approved, disapproved, ongoing, completed, premature terminated), such as:
(a) REC reference numbers;
(b) Names and department of principal investigators;
(c) Application identifiers (e.g. study titles);
(d) Dates of initial submission;
(e) Dates of approval;
(f) Dates of study completion;
(g) Dates of last progress report submission;
(h) Current status of the study.
5.1.2 The secretaries of REC are responsible for maintaining the database and supplying data to any Governing Body(ies) when necessary.

5.2 Records Retention
5.2.1 The REC will retain all necessary documents and records relating to the study, including but not limited to:
(a) documents and records relating to initial review of the study (e.g. initial Research Study Application Form, study documents submitted by the investigators, review meeting agenda and minute, list of reviewers and their conflicts of interest
declaration, relevant correspondences between REC and investigators, and REC written decision(s)/opinion(s);

(b) documents and records relating to continuous oversight of the study (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 Application will be retained for at least 7 years after the completion, discontinuation, termination or withdrawal of the study.

6 Record
Not Applicable

7 Attachment
Not Applicable

8 Reference Documents
Not Applicable