



養和醫療
HKSH Medical Group

倫理委員會(研究)研究申請審查標準操作規程
Standard Operating Procedure for
Review of Research Application for Research Ethics Committee

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Chairman, Research Ethics Committee

HKSH Medical Group

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HKSH V04/ Last Revised : 15/08/2024

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倫理委員會(研究)研究申請審查標準操作規程
Standard Operating Procedure for
Review of Research Application for 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 (“HKSH”) 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 HKSH 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