



養和醫療
HKSH Medical Group

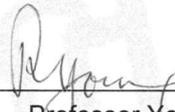
倫理委員會(研究)成員組成標準操作規程
Standard Operating Procedure for
Membership Formation for Research Ethics Committee

Revision Summary of the Last Revision

Version	Revision Details	Relevant Section	Effective Date
01	Initial release	N/A	17 July 2018
03	1. Revised format 2. Renaming from "Group Management Committee" to "HKSH Management Committee"	Whole document	8 October 2019
04	1. Revised name from "HKSH Medical Group" or "Group" to "HKSH" 2. Updated format	Whole document	15 August 2024

Document Locations and Distribution if any

Controlled Soft Copy	Policy Portal in HKSH Medical Group
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15 August 2024

Prepared by : Research Ethics Committee
Approved by Chairman : 15/08/2024
First Issued : 17/07/2018
Next Review : August 2026
Risk Rating : N/A

倫理委員會(研究)成員組成標準操作規程
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 (“HKSH”).

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 HKSH.

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 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 HKSH.

7 Attachment

Not Applicable

8 Reference Documents

Not Applicable