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TITLE : Governance of Research

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1.0 PURPOSE AND SCOPE

1.1. To establish a framework that ensures all research conducted within Union Medical Centre Limited (UMCL), including Union Hospital, is scientifically valid, ethically sound, and compliant with applicable laws and institutional policies, safeguarding the rights and welfare of participants.

1.2. To both govern research conducted within the organization and establish an ethics committee to review research proposals.

1.3. This procedure applies to all clinical and non-clinical research activities involving human subjects, data, tissues, and any collaborative studies conducted in UMCL facilities.

Note: Clinical trials will only be considered with adequate insurance coverage and thorough risk assessment.

2.0 QUALITY OBJECTIVES

To ensure all research at UMCL is conducted with integrity, ethical compliance, and regulatory adherence, promoting participant safety and continuous improvement in research governance.

3.0 REFERENCES

- WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects, World Medical Association. Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and amended by the 64th WMA General Assembly, Fortaleza, Brazil, October 2013
- Wendler, David, "The Ethics of Clinical Research", The Stanford Encyclopedia of Philosophy (Summer 2022 Edition), Edward N. Zalta (ed.)
- Hospital Authority (HA) Guide on Research Ethics (for Study Site and Research Ethics Committee), Operating Guidelines and Guiding Handbook, Revision number 3, Effective 1 October 2018
- Standard Operating Procedure of the Joint CUHK-NTEC CREC, Version No.7, Effective date 03 March 2020
- Code of Practice for Private Hospitals (2024 Edition). Department of Health, HKSAR, China.
- The Australian Council on Healthcare Standards (ACHS) International, The ACHS EQuIP 7 Guide for Hospitals, 2021, Sydney, Australia.
- The Australian Council on Healthcare Standards (ACHS) International, The ACHS EQuIP 7 Advanced Person Centred Systems Module, 2021, Sydney, Australia.
- International Ethical Guidelines for Health-related Research Involving Humans, Fourth Edition. Geneva. Council for International Organizations of Medical Sciences (CIOMS); 2016.
- Guide for Research Ethics Committee Members. Steering Committee on Bioethics (CDBI) of the Council of Europe; 3 December 2010.
- Code of Professional Conduct for the Guidance of Registered Medical Practitioners. Medical Council of Hong Kong; Oct 2022.

4.0 DEFINITIONS AND ABBREVIATIONS

CHM&MD	:	Chief Hospital Manager and Medical Director
DCHM	:	Deputy Chief Hospital Manager
UMCL	:	Union Medical Centre Limited

5.0 RESPONSIBILITIES

The following people have specific responsibilities under this procedure:

Chief Hospital Manager & Medical Director	:	Endorses the overall governance framework and supports the operation of the Ethics Committee, including final endorsement of approvals.
Ethics Committee Chairperson	:	Leads the committee in reviewing research proposals.
Ethics Committee	:	Reviews, approves, rejects, or requests modifications to research proposals based on ethical considerations and applicable standards.
Investigator / Applicant	:	Ensures accurate proposal submission, responsible conduct of research, and adherence to approved protocols.
Ethics Committee Secretary	:	Maintains records, provides administrative support, and monitors adherence to this procedure.
Participant	:	Complies with study requirements after informed consent, reports any issues or adverse effects, and respects the confidentiality and integrity of the research process.
Hospital Management	:	Ensures compliance with legal and regulatory requirements, allocates resources, and oversees governance of research.

6.0 PROCEDURE

6.1 Governance of Clinical Audit

6.1.1 Clinical audits are usually conducted by staff within UMCL for the purpose of reviewing quality and safety of services or serve as Key Performance Indicator indicating area for improvement.

6.1.2 Clinical audit proposals are reviewed and endorsed by the CHM&MD or his representative before commencement. All clinical audits should be registered in the Hospital Audit Registry. SWG 0.2(3) – Submission of Self-initiated Audits in Audit Registry illustrates the vetting process of clinical audits.

6.1.3 Ethics approval is generally not required in these activities, unless the audit results are intended for external publication. In such cases, staff should submit the audit proposal to the Ethics Committee before starting the audit.

6.2 Governance of Clinical Research

6.2.1 Research Proposal Submission: All research proposals must be submitted to the Ethics Committee Secretary and undergo ethical review by the Ethics Committee.

6.2.2 Ethics Review: The Ethics Committee conducts thorough review focusing on participant safety, informed consent, confidentiality, and regulatory compliance.

6.2.3 Approval and Monitoring: No research may commence without Ethics Committee approval. Ongoing research is subject to monitoring and annual reporting.

6.2.4 Compliance: Researchers must comply with this procedure, applicable laws and international regulations relevant to human research.

6.2.5 Data and Record Management: Secure and confidential handling of research data and documents is mandatory.

6.2.6 Responsibility of the Investigator

i) It is the responsibility of the investigator to make sure that ethical approval has been obtained prior to any data collection/analysis taking place.

ii) The investigator shall be accountable to UMCL and must possess scientific qualifications and expertise relevant to the study and clinical care involved. Additionally, the investigator should have a thorough understanding of, and willingness to comply with, all applicable regulatory, professional, and institutional requirements governing research.

iii) Specific responsibilities of the investigator include:

- Plan and execute the study to minimize risks to research subjects to the extent possible.
- Appropriate consideration to the needs of minority groups or vulnerable people.
- Apply to the Ethics Committee for review of proposals and approval before commencing a research.
- Abide by the Ethics Committee decisions including terms of approval and study oversight requirements.
- Provide fair and accurate information (eg costs, time required, side effects and how to withdraw consent) to prospective subjects regarding the nature of research (including the rights and responsibilities of the subjects) and obtain written informed consent from each prospective subject or the subject's legally authorized representative. Recruited subjects should be updated of new information that may be relevant to their willingness to continue participation in the research within specified interval of time as stated in the consent.
- Disclose possible conflict of interest; in particular if an investigator has economic interest in the research outcome, it should be disclosed as part of the consent process.
- Monitor subjects' safety and well-being throughout study. Any significant adverse events must be reported promptly to the hospital management through the Ethics Committee Secretary.
- Ensure safe keeping of study articles.
- Protect the privacy of subjects and confidentiality of data. Keep disclosures to the minimum necessary and anonymize the data.
- Report to the Ethics Committee should there be any deviation or changes to the study. In such case, re-approval prior to continuing the study is required unless the changes is related to eliminate immediate hazards to research subjects or when the change involves purely logistical or administrative.
- The progress of an approved research project should be reported to the Ethics Committee annually. (The Ethics Renewal & Research Progress Report Form (CHM-058) should be submitted.)
- A final report should be submitted by the Principal Investigator to the Ethics Committee at the end of the study.

6.3 The Ethics Committee

6.3.1 The UMCL supports proper research activities by providing robust and responsive ethical review of research through the Ethics Committee.

6.3.2 The Ethics Committee aims to ensure ethical principles are upheld in the UMCL. Apart from reviewing the ethical impact of introducing new procedure / new drugs in the UMCL, one of the primary objectives of the Committee is to review new applications for research and give an opinion on whether the research is ethically sound to safeguards the rights, safety and dignity of research participants. The Committee also advises on legal requirements and international standards related to research.

6.3.3 Members of the Ethics Committee shall meet at least once every year. Ad hoc meetings may be arranged to discuss new research application.

6.3.4 The Committee Members comprise representatives from the UMCL, professional(s) with strong clinical and research background from reputable universities and member(s) of the public whose main professional interest is not in a research area, nor are they a registered healthcare professional. Collectively, these members have the ability and experience to evaluate the scientific, medical and ethical aspects of proposals to be considered. Refer to the updated Terms of Reference of Ethics Committee which also includes current Members of the Ethics Committee.

6.3.5 Avoiding conflict of interest is important when appointing members of the Ethics Committee in order to safeguard the independent review process. When people are appointed to this committee, they must declare any actual, perceived or potential conflicts of interest to the work of the committee and agree to declare if any other conflicts arise subsequently.

6.4 Application and Review Process

Per SWG 0.11(1) Application Procedure for Ethical Approval of Research, various stages are elaborated below:

6.4.1 Submitting an application

For all research conducted within the UMCL, the investigator shall complete the Ethical Approval Form for Research (CHM-057) for ethical approval. The completed application form with all required documents attached e.g. research proposals, informed consent form, study instrument, etc. need to be submitted through the Ethics Committee Secretary. Each proposal undergoes a preliminary screening by the secretariat to confirm that all necessary documentation has been submitted. A study will only be forwarded to members of the Ethics Committee for review when all core documentation has been satisfactorily submitted.

6.4.2 Initial screening by the Ethics Committee

Once the Ethics Committee is in possession of all the necessary documentation, they are pre-reviewed at the secretariat level. Ethical and scientific concerns are raised by members of the Committee, usually through exchanges of emails concerning the protocol, informed consent forms, the scientific peer review process and the study instrument. Based on nature of the research study, expert advice may be solicited from outside the Committee when deemed necessary. Once the secretariat collects all responses from members, the study will be tabled for review in the next Ethics Committee Meeting.

6.4.3 Review at the Ethics Committee Meeting

The Chairperson normally makes a brief presentation of the proposal under review, highlighting the ethical and other issues raised by the study and the documentation provided for review. Other members may supplement the presentation according to their review. The applicant is invited to attend Ethics Committee meeting when discussions on his/ her proposal are taking place. He or she will be given the opportunity to respond to all the queries and comments. After the presentation, the discussion is opened to the rest of the Ethics Committee members, who may raise additional questions. When all the queries are answered, the Committee will make an overall remark until a consensus decision is reached. In cases when consensus cannot be reached, consideration of the proposal shall be postponed to a subsequent meeting in order to seek additional information or expert advice if so decided by members, or the proposal be considered not approved.

6.4.4 The preliminary screening by the Secretary is usually done within 14 working days upon receipt of the application to ensure that all the documentation has been submitted while the initial screening by the Ethics Committee usually takes about three months. Since the proposal will be discussed at the next meeting to the date of receipt of a satisfactory submission, the review time will depend on the schedule of Ethics Committee meeting which is usually held ad-hoc or annually. See SWG 0.11(1) - Application Procedure for Ethical Approval of Research.

6.4.5 After the decision of the Ethics Committee, application will be sent to the Chairperson of the Ethics Committee for review and comment.

6.4.6 Final endorsement by the CHM&MD

Should the application be supported by the Ethics Committee and the Chairperson of the Ethics Committee, the application will be sent to CHM&MD for final endorsement.

6.5 Review Consideration

6.5.1 Proposed study has a reasonable expectation in improving health, healthcare or medical knowledge.

6.5.2 Methodology is scientifically valid and practically feasible.

6.5.3 Risks to subjects are reasonable in relation to anticipated benefits.

6.5.4 Risks to subjects are minimized to the extent possible, such as using procedures that are consistent with sound research design and do not unnecessarily expose subjects to risk. (Radiation safety expert opinion should be sought on any research involving irradiation of human subjects.)

6.5.5 Subject selection is equitable and scientifically based.

6.5.6 Unless qualified for waiver, adequate written informed consent will be sought from each prospective subject or the subject's legally authorized representative.

6.5.7 Adequate explanations are given on the research subjects in the consent form.

6.5.8 There are adequate provisions for monitoring the data collected to ensure safety of subjects.
6.5.9 There are adequate provisions for protecting privacy of subjects.
6.5.10 Sponsor provides adequate indemnity.
6.5.11 When vulnerable subjects are involved, there are necessary additional safeguards to protect their rights and welfare.

6.6 Review Decision by the Ethics Committee

6.6.1 The Ethics Committee has the authority to approve or disapprove a research proposal. Decision of the Committee may include one of the followings:

i) **Approval:** The Ethics Committee will notify applicant in writing stating the
- research and protocol approved including consent form and other relevant documents,
- terms of approval,
- date of approval
- approving authority, and
- approved commencement date of the research

ii) **Conditional Approval, subject to amendments/ clarification/ submission of further documentation:** means that the proposal is approved subject to clarification, incorporation of the required amendments or receipt of some specific documents e.g. submission of informed consent forms into the proposal to the satisfaction of the Ethics Committee. The applicant shall provide the Secretary with a copy of the updated proposal, which shall be considered Approved when the Committee finds that the changes made fulfill the Committee's request.

iii) **Disapproval:** means that the proposal is not approved as submitted because the proposal is not ethically sound. The applicant may resubmit an application to the Committee if the reasons given for disapproval can be corrected and addressed.

6.7 Final Decision

6.7.1 Only upon endorsement from the CHM&MD, the application is considered formally approved. Research should not commence until final endorsement from the CHM&MD is obtained. Outcome of the review will be communicated to the applicant in writing to include any recommendations raised by the Ethics Committee, (and the Chairperson of the Ethics Committee if applicable) and CHM&MD.

6.7.2 The Operating Procedure and related documents will be shared electronically for the purpose of transparency.

7.0 EXHIBITS

Refer to Intranet