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TITLE : Governance of Research

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1.0 PURPOSE AND SCOPE

1.1. This document serves as a guideline to the governance of research in the Union Hospital (UH). UH supports researches aimed at improving the care of patients.

1.2. Research activities include:

1.2.1. Continuous Quality Improvement (CQI) activities such as clinical audits or analysis of existing/ secondary data without identifiers traceable to the subjects; or

1.2.2. Clinical research on human subjects, including but not limited to body tissue & fluid (inclusive of 'waste' or 'extra' tissue and fluid), records & data (inclusive of prior collected data in format linking to individual identifiers), human genome/ stem cell/ pre-implantation & human embryo research and collection & storage of 'extra' material for future study.

1.2.3. Research study that may or may not be funded by/ collaborated with a body outside of the UH, for planning of publication, which has an impact on non-participating staff and/ or patients.

1.2.4. Research study should preferably have prior ethical approval from a tertiary educational institution, (e.g., The Chinese University of Hong Kong or The University of Hong Kong, etc.), OR a research project initiated by the Union Hospital Management.

Note: Clinical trials will only be considered for collaboration at multicentre level with full ethics approval by other tertiary institutions with adequate insurance coverage and thorough risk assessment.

2.0 QUALITY OBJECTIVES

2.1. To develop a sound ethical framework for conducting clinical research, the Hospital takes reference to both international and local standards in creating its framework for considering and vetting a research proposal.

3.0 REFERENCES

- ISO 9001:2015 – 7.5 Documented information
- ISO 9001:2015 – 8.3 Design and development of products and services
- SWG 0.2(3) Submission of Self-initiated Audits in Audit Registry
- SWG 0.11(1) Application Procedure for Ethical Approval of Research
- Terms of Reference of Ethics Committee
- 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
- Human Ethics, Li Ka Shing Faculty of Medicine, The University of Hong Kong
- Code of Practice for Private Hospitals (2022 Edition). Department of Health, HKSAR, China.
- The Australian Council on Healthcare Standards (ACHS) International, The ACHS EQulP 7 Guide for Hospitals, 2021, Sydney, Australia.
- The Australian Council on Healthcare Standards (ACHS) International, The ACHS EQulP 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; Jan 2016.

4.0 DEFINITIONS AND ABBREVIATIONS

CHM&MD	:	Chief Hospital Manager and Medical Director
CQI	:	Continuous Quality Improvement
DCHM	:	Deputy Chief Hospital Manager
UH	:	Union Hospital

5.0 RESPONSIBILITIES

The following people have specific responsibilities under this procedure.

CHM&MD	:	Final endorsement of the new research application.
DCHM	:	To review and comment on eligibility of new application of research.
Ethics Committee	:	To review and give opinion for new applications of research. : To approve or disapprove a research proposal. : To advise on legal requirements and international standards.
Investigator / Applicant	:	Responsible to overall research subject activities.
Ethics Committee Secretary	:	To handle new applications of research procedure. : To communicate with investigator / Applicant on the progress and result of the application(s). : To receive reports of significant adverse events and report to the hospital administration. : To record and file all research applications and related documents.
Participant	:	To be compliant with research protocol and inform research team in case of any injury or development of any new medical conditions as soon as possible.
Hospital Administration	:	Governance of Research.

6.0 PROCEDURE

6.1 Governance of Clinical Audit

- 6.1.1 Clinical audits are usually conducted by staff within UH 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 of the study. All clinical audits should be registered in the Hospital Audit Registry for monitoring and tracing of the progress. 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 usually not required in CQI activities, unless the result of the audit is intended for external publication. Should this be the case, staff should submit a proposal of the audit to the Ethics Committee prior to the commencement of the study. The Ethics Committee will advise whether it is appropriate to submit the audit for publication. The Ethics Committee may or may not require the consent from patients, which is mainly for prospective studies and rarely for retrospective studies for publication purpose. From research experience, the consent from patient is usually easy to obtain from subjects participating in prospective studies.

6.2 Governance of Clinical Research

The purpose of research governance is to ensure research integrity through accountability, transparency and responsibility. Ethics review is a mandatory process, as this type of study usually incurs additional risk, burdens and/or intrusion of privacy and possible overlap among similar projects.

6.2.1 Clinical Research Compliance

All human research conducted within the UH meets the highest ethical, scientific, regulatory and professional governance standards; and complies with relevant Hong Kong legislation, UH guidelines and policies, medical and scientific professional codes of conduct.

- i) International guidelines: WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects
- ii) The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use – Guideline for Good Clinical Practice
- iii) Code of Professional Conduct for the Guidance of Registered Medical Practitioners. Medical Council of Hong Kong; Jan 2016.

6.2.2 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 should be answerable to the UH and should
 - Qualify scientifically, proficient in the area of study and care involved; and
 - Ethically understand and willing to comply with regulatory, professional and institutional requirements on research.
- iii) Specific responsibilities of the investigator include:
 - Plan and execute 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 administration 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.
 - Advise 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 UH 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 UH. Apart from reviewing the ethical impact of introducing new procedure / new drugs in the UH, 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 meeting may be arranged to discuss new research application.
- 6.3.4 The Committee Members comprise representatives from the UH, 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 UH, 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 Ethics Committee Meeting

The Chairman 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 DCHM Office for review and comment.

6.4.6 Final endorsement by the CHM&MD

Should the application be supported by the Ethics Committee and DCHM Office, 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 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 DCHM 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 RECORDS AND FORMS

7.1 The following records are retained by the Ethics Committee:

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| • <u>Ethical Approval Form for Research</u> | Form | CHM-057 |
| • <u>Ethics Renewal & Research Progress Report Form</u> | Form | CHM-058 |

8.0 EXHIBITS

Refer to Intranet