Announcement

Faculty of Medicine, Chulalongkorn University

Subject: Policy on Research Ethics Involving Human Participants

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To ensure the effective governance of research ethics involving human participants conducted by personnel of the Faculty of Medicine, Chulalongkorn University (MDCU) and King Chulalongkorn Memorial Hospital, Thai Red Cross Society (KCMH) as well as by researchers from other research/academic institutions who intend to conduct research involving human participants within MDCU and/or KCMH, and to promote the responsible conduct of research in accordance with international ethical standards that protect the rights, safety, dignity, welfare and privacy of research participants, the Faculty of Medicine, Chulalongkorn University hereby establishes the following policy on research ethics involving human participants.

1. Definition

"Research" refers to the systematic process of investigation conducted with the objective of acquiring new knowledge, developing/ designing and optimizing methods for disease prevention and treatment, medical devices, or related activities. The mentioned research may result in academic publications, commercial applications, policy development or reform, as well as the provision of testing or analytical services that contribute to knowledge advancement, including the transfer of research outputs that result in the development of new medical devices, therapeutic approaches, as well as the innovation of services and activities.

"Research involving human participants" refers to the systematic process of investigation to acquire knowledge related to human beings through interventions involving physical, mental, cells, organelles, genetic materials, biological specimens, tissues, fluids, and secretions, as well as medical records or health–related information of participants. The objective is to advance knowledge in the fields of biomedical sciences, public health, health sciences, behavioral sciences, social sciences, or humanities in relation to health. This definition shall also include research involving deceased individuals.

" Office" refers to the Office of Research Ethics, Faculty of Medicine, Chulalongkorn University

"Committee" refers to the Institutional Review Board, Faculty of Medicine, Chulalongkorn University

" Researcher" refers to faculty members, researchers, physicians, resident/ clinical fellows, graduate students in all disciplines, medical students, personnel of the Faculty of Medicine, Chulalongkorn University and personnel of King Chulalongkorn Memorial Hospital, Thai Red Cross Society, as well as individuals who are not affiliated with either MDCU or KCMH, but intend to conduct research within MDCU and/or KCMH.

"Research Participant" refers to an individual who meets the eligibility criteria specified by the research protocol, has been adequately informed to make the consent/assent to participate in the research voluntarily.

2. The Faculty of Medicine mandates that all research involving human participants must be reviewed and approved by the Committee. Furthermore, monitoring measures shall be established to ensure compliance accordingly.

3. The Faculty of Medicine requires the Committee to review submitted research proposals that involve human participants to ensure compliance with international standards, applicable laws, and the regulations of the Faculty of Medicine and Chulalongkorn University.

4. The Faculty of Medicine assigns the Committee the authority to oversee and conduct post-approval reviews of ongoing research involving human participants at intervals appropriate to the level of risk posed to research participants. The Committee also has the authority to suspend or terminate any research if it is later found that the research is no longer complying with the criteria established at the time of approval, in order to protect the rights and welfare of research participants.

5. The Faculty of Medicine mandates that the Committee's review and decision-making processes shall be conducted independently. In the event that a project is not approved, such a decision shall not be overruled by any person or entity other than the Committee.

6. The Faculty of Medicine shall provide adequate facilities, infrastructure, resources, and an environment necessary for the conduct of human research ethics activities, ensuring they are sufficient, appropriate, and in compliance with applicable laws and regulations, to guarantee the Committee's effective operation.

7. The Faculty of Medicine shall extend sufficient legal support to the Committee to carry out its activities, including legal assistance in cases where the Committee is subject to judicial proceedings related to its operations.

8. The Faculty of Medicine requires the Committee to disclose any conflicts of interest or competing interests and to refrain from participating in the decision of any research involving human participants proposals in which such conflicts may exist. In full board meetings, all Committee members and attendees must disclose any potential conflicts of interest prior to the commencement of the meeting.

9. The Faculty of Medicine shall establish measures to ensure appropriate care for research participants in the event that they suffer harm directly resulting from their participation in the research.

10. The Faculty of Medicine requires researchers conducting clinical trials to register their research projects in a database of clinical trial registry that complies with international registration standards to ensure transparency in research conduct.

11. The Faculty of Medicine mandates that the Office establish systems or channels of communication to enable researchers, research participants, and other stakeholders to inquire, raise concerns, or file complaints regarding unethical conduct in research, rights, and the ethics review process. These channels must be easily accessible, convenient, and free from complicated procedures, with timely responses provided.

12. The Faculty of Medicine shall establish a fact-finding and investigating process for complaints concerning research misconduct. The process shall be conducted in accordance with the disciplinary principles and procedures of the Office, with appropriate measures imposed on

researchers found to have engaged in unethical conduct. Such measures shall be applied reasonably and in a manner consistent with the circumstances and the intent of ethical oversight.

13. The Faculty of Medicine shall routinely organize training sessions on research ethics to promote the development of knowledge and awareness among researchers. All researchers are required to undergo training in Human Subject Protection, Good Clinical Practice (ICH focus), and other relevant courses prescribed by the Office. Researchers are also encouraged to engage in regular refresher training to ensure that research is conducted ethically. Researchers must provide valid proof of such training to the Committee when submitting research proposals for ethical review.

14. The Faculty of Medicine shall establish standards for the archiving of the documents, including the duration for which documents must be retained, as well as standards for data security and confidentiality.

15. The Faculty of Medicine requires the Office to disclose the list of approved proposals along with the names of the researchers responsible for the projects.

16. The Faculty of Medicine may require both internal and external surveyors for evaluation. The Office is committed to monitoring the outcomes and recommendations of such evaluations to ensure continuous quality improvement of the Committee.

This announcement is hereby made for acknowledgement and compliance by all concerned.

Announced on 8 July 2025

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