



**Announcement of King Mongkut's University of Technology Thonburi
on Human Subjects Research Governance
B.E. 2559 (2016)**

“Research & Development” is a key mission of King Mongkut's University of Technology Thonburi and one of KMUTT's vision is to “strive towards excellence in technology and excellence”. In order to develop and promote research potential to be in compliance with international standards, the development of ethics and morality applications in human subjects research is thus necessary for the development of research quality and research standard relating to human subjects research for researchers at KMUTT, which requires the consideration of research ethics, rights protection, safety, and minimization of risks that may have negative impacts on research participants.

By virtue of the provision under Section 27 (8) of King Mongkut's University of Technology Thonburi Act B.E. 2541 (1998) in accordance with the resolution of the Academic Council Meeting No. 3/2559 (2016) on 14 March 2016 and the resolution of the University Council of KMUTT No. 204 on August 3, 2016, it is thus resolved that the announcement be given as follows:

Clause 1 This Announcement shall be called the “Announcement of King Mongkut's University of Technology Thonburi on Human Subjects Research Governance B.E. 2559 (2016)”

Clause 2 This Announcement shall come into force and effect within one hundred and eighty (180) days from the date on which it is given.

Clause 3 In this Announcement:

“KMUTT”	means	King Mongkut's University of Technology Thonburi
“Academic Council”	means	the Academic Council of KMUTT
“President”	means	President of KMUTT
“Committee”	means	KMUTT-Institutional Review Board

“Office”	means	Research, Innovation, and Partnerships Office of KMUTT
“Researcher”	means	Employees, civil servants, adjunct staff, students of KMUTT who hold the position of principal investigator
“Human Subjects Research”	means	The conducting of a study, research, inquiries, and interviews in social studies, the environment, and various environmental conditions, experimentation of agricultural products, food products, pharmaceutical products, or medical tools, study of the nature of diseases, diagnosis, treatment, promotion of health and disease prevention relating to or with humans, study and research on medical records or database, sample materials, secretions, tissue obtained from the human body and others, including the study of physiology, biochemistry, parasitology, responses to physical and psychological treatments in normal participants or patients
“Research Project”	means	A Systematic Investigation based on research or study to establish new knowledge and understanding that may be distributed and generally applied (Generalizable Knowledge)
“Practice Guidelines”	means	Practice Guidelines for ethics in conducting human subjects research at KMUTT

Clause 4 The KMUTT-Institutional Review Board comprises:

4.1 Chairman, who shall be appointed by the President from employees, civil servants, retired employees or retired civil servants of KMUTT.

4.2 Internal Committee shall consist of between five and ten persons and be selected from employees, civil servants, staff, retired employees or retired civil servants of KMUTT, which the faculty or any other unit under a different name that is equivalent to the faculty nominates to the Academic Council for consideration and selection.

4.3 External Committee shall consist of at least the same number of Internal Committee members, who are not employees, civil servants and staff of or who hold any position in KMUTT, which the Chairman and Senior Vice President for Research and Innovation jointly consider and nominate to the Academic Council for selection. The External Committee shall comprise:

4.3.1 At least one research ethics expert.

4.3.2 At least one medical or medical science expert.

4.3.3 At least one lay person representative.

4.4 The Academic Council shall select one member of the Internal Committee to hold the position of Vice Chairman of the Committee.

4.5 The Director of the Office shall hold the position of Secretary, and shall appoint a staff member of the Office to serve as Assistant Secretary.

Clause 5 Powers and Duties of the Committee:

5.1 To consider and approve or disapprove research projects, require revisions, or terminate approval of research projects in cases where the research does not comply with the Practice Guidelines.

5.2 To monitor the progress of research projects through progress reports in relation to Morality and human ethics research.

5.3 To provide recommendations to researchers for improving research projects in accordance with the principles of human research ethics.

5.4 To establish rules, Practice Guidelines, administrative mechanisms, and procedures relating to the review of human research projects.

5.5 To suspend, withdraw approval, or terminate research projects in cases where the research project may expose research participants to greater risks than anticipated, or where there is serious and/or continuing non-compliance with ethical principles, or serious and/or continuing non-compliance with the Committee's requirements.

5.6 To restrict certain parts of the research activities (Restriction) in cases where the researcher fails to comply with ethical principles or the Committee's requirements. Permission to continue the research shall be granted once the researcher has fully complied with such requirements.

5.7 To appoint subcommittees comprising individuals with diverse knowledge or experience in order to ensure broad and comprehensive perspectives in all aspects of the research, to perform any acts within the powers and duties of the Committee.

5.8 To prepare an annual report for submission to the President upon approval of the Academic Council, through Senior Vice President for Research and Innovation.

5.9 To prepare reports on special case reviews for submission to the President upon approval of the Academic Council, through Senior Vice President for Research and Innovation, within thirty days from the date of the meeting, due to the following circumstances.

5.9.1 Serious Adverse Events or Unanticipated Problems, where there are reasonable grounds to believe that such events or problems may be related to the research.

5.9.2 The researcher fails to conduct the research in accordance with the protocol approved by the Committee, or fails to comply with the Committee's Practice Guidelines (Non-Compliance), and such non-compliance is repeated and may cause harm to research participants.

5.10 To undertake other matters relating to the supervision of Human Subjects Research.

5.11 To undertake any act as assigned by the President.

In performing their duties, the Committee members shall dedicate their knowledge, abilities, and responsibilities to researchers, research participants, research subjects, and KMUTT in order to ensure and monitor that research conducted within KMUTT is carried out in compliance with research ethics principles, for the welfare of all persons involved in the research projects and for the preservation of the honor and dignity of KMUTT.

Clause 6 Qualifications of the Committee Members:

6.1 The member shall hold at least a bachelor's degree in one of the following fields: science, medical science, social science, behavioral science, humanities, or other related fields, except for external members who are Lay Person and who may be community leaders or persons with specific knowledge and experience.

6.2 The member shall possess knowledge of human research ethics or have completed training in human research ethics in order to understand ethical principles and guidelines for ethical review and assessment of research.

6.3 The member shall possess diverse knowledge and expertise and/or experience relevant to the research projects under review in order to ensure broad and comprehensive perspectives in all aspects of the research.

6.4 The member shall possess integrity and research ethics and shall comply with KMUTT's Code of Conduct.

Clause 7 Term of the Committee Members

7.1 The term of the Committee members is three years from the date of appointment. A member who vacates office may be re-appointed.

7.2 In addition to vacating office on the expiration of the term, a member shall vacate office upon:

- (1) Death
- (2) Resignation
- (3) Lacking any of the qualification provided in Clause 6
- (4) Being sentenced by a final judgment to imprisonment, except for an offense committed through negligence or a petty offense
- (5) Being adjudged bankrupt
- (6) Being an incompetent person or a quasi-incompetent person
- (7) Failure to perform duties, misconduct, or legal incapacity

7.3 In the event that a Committee member vacates office before the expiration of the term and no replacement has yet been appointed, the remaining Committee members may continue to perform their duties.

Where a vacancy occurs before the expiration of the term, a replacement shall be appointed within thirty days. The replacement member shall hold office for the remaining term of the replaced member, unless the remaining term is less than one hundred and twenty days, in which case a replacement appointment may not be made.

7.4 In the event that the Committee members vacate office upon expiration of the term but the new Committee members have not yet been appointed, the outgoing Committee members shall continue to perform their duties until the new Committee members have been appointed.

Clause 8 A meeting of the Committee shall require the attendance of not less than one-half of the total number of members entitled to attend the meeting in order to constitute a quorum.

At a meeting, if the Chairperson is absent or unable to perform his/her duties, the Vice Chairperson shall preside over the meeting. If both the Chairperson and the Vice Chairperson are absent or unable to perform their duties, the members present at the meeting shall elect one member to preside over the meeting.

Voting shall be conducted openly, unless a majority of the meeting resolves that the vote be conducted in secret. The method for conducting a secret vote shall be as prescribed by the Chairperson of the meeting.

Clause 9 In the event that the Committee resolves not to approve or to terminate the approval of a research project on the grounds that the research does not comply with human research ethics, the researcher shall have the right to clarify the issues and revise the research project and resubmit it to the Committee within sixty days from the date of receipt of the Committee's notification of the review result. The Committee shall complete the reconsideration within thirty days from the date of receipt of the clarification letter. If the reconsideration cannot be completed within such period due to necessity, the Committee shall notify the researcher in writing before the expiration of such period. In such case, the reconsideration period may be extended for not more than thirty additional days from the expiry date.

Clause 10 If, upon reconsideration under Clause 9, the Committee still resolves not to approve or to terminate the approval of the research project on the grounds that the research does not comply with human research ethics, the researcher shall have the right to appeal to the President within thirty days from the date of receipt of the notification of the reconsideration result. The President shall appoint a panel of committees to consider the appeal and provide recommendations to the President for final decision. The appeal review shall be completed within sixty days from the date of receipt of the appeal letter. The decision of the President shall be final.

Clause 11 Powers and Duties of KMUTT

11.1 KMUTT shall announce policies and Practice Guidelines for the oversight of Human Subjects Research Projects within KMUTT.

11.2-KMUTT shall not permit the conduct of any research project that has been submitted but has not received approval from the Research Ethics Committee.

11.3 KMUTT shall be legally responsible for the Committee's performance of duties conducted in good faith within the scope of authority defined in this Announcement.

11.4 KMUTT shall provide support to ensure the Committee can operate independently, fairly, and free from interference by the executives.

11.5 KMUTT shall provide adequate resources, including personnel, materials, information resources, information technology tools, equipment, premises, and budgets, to the Committee to ensure its efficient operation.

11.6 KMUTT shall calculate the workload for the Committee members who are KMUTT staff, civil servants, or employees according to the KMUTT's standard criteria.

Clause 12 Duties of Researchers

12.1 This Announcement shall apply to all human research projects in which a KMUTT researcher serves as the principal investigator.

12.2 The researcher has a duty to study and strictly comply with the Practice Guidelines of KMUTT.

Clause 13 In the event of any issue arising from reporting under Clause 5.9, or relating to the implementation, or interpretation of this Announcement, the President shall have the authority to decide such matter, and such decision shall be final.

Transitional Provision

Clause 14 KMUTT shall complete the appointment of the Committee members within sixty days from the date of this Announcement.

Clause 15 The Committee shall prescribe the criteria, Practice Guidelines and management mechanisms for the review of Human Subjects Research Projects within one hundred and eighty days from the date of this Announcement.

Announced on September 16th, 2016.

(Associate Professor Dr. Sakarindr Bhumiratana)

President of King Mongkut's University of Technology Thonburi