



Mahidol University Announcement
Guidelines for Submission of Research Projects
for Human Subject Research Ethics Review,
B.E. 2567 (2024)

As deemed appropriate, this announcement is issued to establish clear guidelines for teaching staff, researchers, staff members, and students of Mahidol University for submission of research projects for human subject research ethics review either to the relevant Institutional Review Board or the Central Institutional Review Board, Mahidol University to ensure the orderly and appropriate operation.

By virtue of Section 34 (1) of Mahidol University Act, B.E. 2550 (2007) and the resolution of the Policy Committee on Research and Academic Ethics, Mahidol University from Meeting no. 4/2023 on 7 December 2023, the announcement is issued with details as follows:

Article 1 In this announcement,

“University” refers to Mahidol University.

“Institution” refers to the Office of the University Council, Office of the President, campuses, faculties, and other institutions under different designations with status equivalent to a faculty.

“Department” refers to the departments designated by the university to operate under an institution.

“Staff member” refers to staff members employed to work full-time by Mahidol University.

“Student” refers to Mahidol University’s students.

“Trainee” refers to Mahidol University’s staff members and students, as well as resident doctors.

“IRB of Record” refers to the relevant Institutional Review Board of the Institution to which the project leader is affiliated or the Central Institutional Review Board (in case the institution to which the project leader is affiliated does not have its own institutional review board). IRB of Record is responsible for supervising research projects that involve multiple institutions and coordinating among the relevant institutional review boards within the university to minimize redundancy in the research project submission for human subject research ethics reviews.

Article 2 This announcement shall apply to the institutions, departments, staff members, and students. The implementation of this announcement shall comply with the regulations, guidelines, and announcement issued by the university.

Article 3 Researchers wishing to submit the research project for ethics review must meet the following qualifications.

3.1 They must be the project leader or the principal investigator (PI) who is a staff member of the university.

In case the research project is part of a curriculum or is conducted for the completion of a degree, the student or trainee of the university may be assigned as the principal investigator, provided that his/her research advisor is named as a co-investigator (CO-I). In this case, the research advisor must co-sign, with the principal investigator, all documents relevant to the project submitted to the institution review board so that the university can supervise and take responsibility for the project.

3.2 The project leader or the principal investigator, as well as all the co-investigators, must have received a training in human subject research ethics and submit a valid certificate or proof of a training completion to the relevant institutional review board. The certificate must not expire or be issued within the past three years from the training date.

Article 4 The guidelines for research project submission for human subject research ethics reviews are as follows:

4.1 In case the institution to which the project leader or the principal investigator is affiliated has its institutional review board, the research project shall be submitted for review to his/her institutional review board.

4.2 In case the institution to which the project leader or the principal investigator is affiliated does not have its institutional review board, the research project shall only be submitted for review to the Central Institutional Review Board, Mahidol University.

4.3 In case the project leader submits a research project that involves multiple institutions within the university, the research project shall be submitted for reviews either to the institutional review board of the project leader's affiliated institution or the Central Institutional Review Board, Mahidol University in accordance with the guidelines 4.1 and 4.2. The institutional review board of the project leader's affiliated institution or the Central Institutional Review Board receiving the project will serve as the IRB of Record and will coordinate with relevant ethical review committees within the university for the joint reviews and evaluation of the project. The project leader is required to submit report only to the IRB of Record.

4.4 In case an external individual is the project leader or the principal investigator of a research project conducted within Mahidol University, a member of the university must serve as the co-investigator of the project. The research project must be submitted for reviews to the institutional review board of the affiliated institution of the project leader (if applicable).

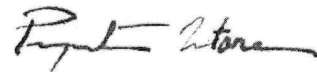
In addition, a letter of permission to conduct the research project issued by the affiliated institution of the project leader must be submitted to the head of the institution within Mahidol University. The head of the institution may seek opinions from the relevant Institutional Review Boards, or the Central Institutional Review Board as stated in 4.1 and 4.2.

If the affiliated institution of the project leader does not have its institutional review board, the member of the university who is the co-investigator of the project may submit the research project for ethics review on behalf of the project leader to either his/her Institutional Review Board of an institution or the Central Institutional Review Board as stated in 4.1 and 4.2.

Article 5 Should there be any difficulty in implementation according to this announcement, the arbitral power shall be made at the discretion of the president of the university, and his decision is considered final.

Henceforth, this announcement shall be in effect.

Issued on **5** November 2024



(Professor Piyamitr Sritara, MD, FRCP)

President of Mahidol University