

**Announcement of Mahidol University  
On Policy to Manage Research on Humans  
B.E. 2551**

Mahidol University realizes the importance of protecting the rights and welfare of those who participate in research on humans under its administration. Such research must be in accordance with accepted international ethical principles, as stipulated by the National Research Council and which includes an acknowledgement of Thai traditions and customs, resulting in quality research that is recognized internationally and engenders confidence in those who will participate in the research.

By virtue of Section 24(2) of the Mahidol University Act B.E. 2550, the Council of Mahidol University and the President, at the 415<sup>th</sup> meeting on 21 May B.E. 2551, promulgated certain policies in research on humans, in accordance with international standards, for every Department of the University.

1. In this Announcement

“University” means Mahidol University;

“University Council” means the Council of Mahidol University;

“President” means the President of Mahidol University;

“Institution” means the Office of the President, Campus(es), Faculty(ties), Graduate College(s), College(s), Institute(s), School(s), Center(s) and any other division with the status equal to a Faculty;

“Head of the Institution” means the Vice President(s) appointed by the President to oversee Campus(es), Dean, Director of College, Institute, School, Center or the head of any other division with the status equal to a Faculty or any person appointed by the Head of an Institution;

“Authorized Person” means the President or any person appointed by the President or Head of an Institution;

“Head of Research Project” means any person conducting work within the University or whom the University invites or appoints or approves to do research for the University and who holds the duties to manage research projects;

“Research on Humans” means the study on living human beings, the study of samples of human beings that may identify the persons who own such samples (blood, secreted substances, tissues and others), study through private information that points towards particular persons with the objective of acquiring new knowledge in different areas in order to improve the living conditions and quality of life of human beings;

“Approval of the Ethical Committee on Humans” means the approval that a research project receives because it protects the rights and welfare of those who participate in the research.

2. The University supports the establishment of the Committee on Ethical Research on Humans in line with international principles. This Committee and the Head of the Institution are independent from one another.

2.1 An Institution has the capacity to establish its own Committee on Ethical Research on Humans if it conducts not less than 100 projects per year;

2.2 The Authorized Person for the appointment of an Institutional Committee on Ethical Research on Humans is the Head of an Institution; for the University Committee on Ethical Research on Humans, the Authorized Person is the President;

2.3 The Committee on Ethical Research on Humans consists of

2.3.1 not less than 5 persons

2.3.2 at least one person from outside the University as a Committee member

2.3.3 each committee member must possess knowledge and experience in a particular discipline, including medical science and public health, social science, research methodology and ethical research on humans in order to evaluate all aspects of the research projects,

2.3.4 the committee will be comprised of men and women with diverse academic backgrounds,

2.4 The relationship between the Institutional and University Committees on Ethical Research on Humans

2.4.1 The Committees on Ethical Research on Humans may act independently, without any interference from each other,

2.4.2 The Head of an Institution may disapprove of a research project which has been endorsed by the University Committee on Ethical Research on Humans if the research project is in conflict with the policies or regulations of the Institution. However, the Head of an Institution may not approve a research project which has not been approved by the University's Ethics Committee,

2.4.3 The Institution/University should provide sufficient resources, including human resources, training, equipment, infrastructure and funding, to ensure the effective administration of research projects approved by the Committees on Ethical Research on Humans,

2.4.4 The Institution/University shall be legally liable for the Committees on Ethical Research on Humans that faithfully review and consider research projects and make compensation in case a civil lawsuit has taken place.

3. The Institutional Committee on Ethical Research must be registered, in accordance with the directives of the University, and must notify the President.

4. Research projects on humans, within the scope specified, shall be considered and approved by the Committees on Ethical Research on Humans that are registered with the University prior to starting the work. The scope of such research projects are as follows:

4.1 Research projects administered or co-administered by staff of Mahidol University conducted either within or outside of the University;

4.2 Research projects administered by outsiders but conducted within the University or using information or samples that point towards particular persons, with the approval to do research within the premises of the University by the Head of the Institution or equivalent competent official from the University;

4.3 Types of research projects which need approval prior to starting the work are as follows:

- 1) Clinical research related to pharmaceuticals or medical devices,
- 2) Research related to diagnosis and radiation therapy,
- 3) Research related to methods of operations,
- 4) Research that uses samples from human bodies,
- 5) Research projects from patient information to which data accumulation processes are linked and may affect a person,
- 6) Research on pandemics,
- 7) Research with the principle researcher as a health care provider and with processes in the research having effects upon personal health, incurring the risk of being subject to a lawsuit,
- 8) Research in social science, humanities, or psychology undergoing any survey, interview, behavioral observation and data which is undisclosed to the public and is personal.

5. The Committee on Ethical Research on Humans shall set the standard operating procedures and the investigation and monitoring of research projects as well as their reporting

5.1 The Committee on Ethical Research on Humans shall set the standard operating procedures for every research project with transparency and accountability, with a focus on the following issues

- Goal of the Committee on Ethical Research on Humans
- Ethical principles of research on humans that the Committee uses as its reference
- Authority and functions of the Committee on Ethical Research on Humans
- Qualifications and selection of appropriate persons to serve on the Committee on Ethical Research on Humans
- Executive support given to the Committee on Ethical Research on Humans
- Supporting staff within the Office of the Committee on Ethical Research on Humans
- Meeting dates
- Procedures of approval and resolution
- Result notification processes
- Documents to be submitted to the Committee on Ethical Research on Humans
- Archives and other documents relating to the operation
- Approval and revision of the administration of the Committee on Ethical Research on Humans

5.2 The Committee on Ethical Research on Humans shall have the following authority and functions

5.2.1 Approves or not approves research projects or requests revisions prior to approval by considering the following

- Qualifications of researchers
  - Other factors for research, such as research assistants, tools, facilities and infrastructures
  - Research methodology
  - Benefits and risks of the research
  - Procedures for research participant consent
  - Any judgment will be of uniform standard, be it for a new research project that has never been approved by the Committee on Ethical Research on Humans or a research project that was approved by the Committee on Ethical Research on Humans from another institute, as in the case of a multi-centered study
- 5.2.2 Follows the progress of the research project operation at least once a year, or more as appropriate, until the research ends and further requests that researchers report unwanted circumstances that occurred to the Committee on Ethical Research on Humans within the specified time. The Committee will review the drafts of research projects, with a focus on their benefits and risks
- 5.2.3 Requests that the research temporarily cease or stop approval of the research project in the following cases
- Harm to research participants from unforeseeable causes
  - The researcher intentionally violates the conditions of the project as proposed to the Committee on Ethical Research on Humans without notification of the reason or causes harm to research participants due to a violation of research project conditions

During this cessation period, researchers may not accept any new researchers or participants and must cease the work of the initial researchers and participants. However, the research project may continue, with the aid of the initial researchers, if the human subjects in the research require continuing medication.

During this cessation period, the Committee on Ethical Research on Humans will investigate the conduct of the researchers and any unwarranted circumstances that occurred in order to be fair to the researchers and participants before approving or ceasing to approve the continuation of the research project. The Committee on Ethical Research on Humans may request that researchers revise their methodology or increase monitoring measures to ensure the safety of research participants in case the project continues.

If the Committee on Ethical Research on Humans decides to cease the operation of a research project, the researchers, fund providers and executives of the Institution, in particular the Dean/Director, Vice President of Research, and the President, will be notified. A research project that no longer has the approval of the Committee on Ethical Research on Humans will not be permitted to operate within the University.

- 5.2.4 Stipulates restrictions or increases measures in order to ensure safety in research procedures subsequent to the temporary cessation of research if it finds that researchers have violated the conditions of the research project and notified the Committee on Ethical Research on Humans that there was no severe harm to research participants, in

accordance with ICH-GCP principles. The Committee on Ethical Research on Humans may request that researchers increase preventive measures so that no mistake reoccurs prior to the new approval

#### 5.2.5 Report of the results of operations by the Committee on Ethical Research on Humans

The Institutional Committee on Ethical Research on Humans will report yearly (Jan–Dec) the results of operations to the Head of the Institution or University every February

### 5.3 The administrative responsibilities of the Institutional Committee on Ethical Research on Humans

#### 5.3.1 Set meeting dates

The Committee should set up meetings not less than 6 times/year or once every 2 months and notify all concerned parties about the meeting date and time

#### 5.3.2 Consideration of research projects

- New research projects require the following
  - 1) Research design and methodology should be appropriate to provide information in line with the objectives set and the statistical methods used in order to calculate the minimal number of research samples for significant statistical analysis
  - 2) Criteria for the selection of research participants
  - 3) Criteria by which to cease either individual or group projects
  - 4) Appropriateness of infrastructure for research in terms of area, tools, research assistants, and the administrative capacity in case of an emergency
  - 5) Responsibility towards research participants in unwarranted circumstances
  - 6) Consent procedures for participation in research, including access, consent for research participation, provision of information and questions and answers for research participants, complete documentation, and notification to research participants (if any) or the media in providing adequate information
  - 7) Special care for vulnerable subjects who may not be able to make their own decisions, such as children or juveniles, pregnant women and babies, patients with chronic diseases, patients under emergency or intensive care conditions, elders, students, undergraduates, employees, supervisees of researchers, prisoners, etc.
- If research projects have been approved, researchers shall contact the Committee on Ethical Research on Humans subsequent to approval as follows

- 1) For revision of research projects, researchers may begin the operation subsequent to when such revision has been approved. Subsequently, researchers may start the research with the participants and shall obtain consent for every revision that may affect them
- 2) Researchers shall notify the Committee on Ethical Research on Humans of unwarranted occurrences within the specified time. The Committee shall consider such reports and notify the researchers as to whether the research shall continue
- 3) Researchers shall submit a progress report to the Committee on Ethical Research on Humans at least once a year. In the case of research projects with high risks, the Committee shall request progress reports more frequently in accordance with its resolution. If researchers fail to submit a progress report as specified, the Committee may consider reversing its approval for the research project.

#### 5.3.3 Acceptance of research projects entails 2 categories

1) A research project presented to the quorum of the Committee  
Each research project requires the appointment of 2 primary reviewers who will present details of the project, including recommendations, at a Committee meeting. Subsequently, there shall be a meeting of resolution to approve or not approve the research project. The resolution must be made by a quorum of the Committee, consisting of at least 5 members, with at least 1 outsider and one medical doctor in case of biomedical research. If the quorum is not met, the meeting may not continue. If any committee members are unavailable, they must notify the chairman, vice chairman or secretary prior to the meeting time to determine if a quorum exists to approve or not approve the research project in line with international standards. A committee with the right to vote is the one sitting in the meeting only; the project will be approved only with a unanimous decision or majority support if unanimity is not reached. If any committee members have a vested interest in the proposed research project, either positive or negative, they must exempt themselves from the decision-making process. However, they do have the right to explain their reasons.

#### 2) Expeditious review of research projects

There may be research projects with low risks to research participants; therefore, such research may be reviewed expeditiously by the chairman of the Committee on Ethical Research on Humans. This unilateral action will save time and resources in considering a project. In addition, the

chairman may delegate any committee member with expertise and experience to unilaterally approve a research project. The Committee on Ethical Research on Humans, in light of these expeditious reviews, may approve research projects without bringing the issue to a formal meeting. However, if approval is not granted for any reason, the research project must be submitted to the full Committee.

#### 5.3.4 Results of the Committee's consideration and notification of research projects submitted for approval

Results of the Committee's consideration are categorized into 4 types

Category 1: Approval without revision

Category 2: Approval in principle, but the approval will only be given upon revision, in accordance with the recommendations of the Committee on Ethical Research on Humans, or with additional explanation

Category 3: Delayed approval awaiting the Committee's decision subsequent to revision

Category 4: No approval, with reasons specified

The Committee on Ethical Research on Humans will issue a written notification of its decision within 2 weeks subsequent to the meeting.

#### 5.3.5 Guidelines for approving research on humans

The Committee on Ethical Research on Humans shall prepare guidelines for the approval of research projects in order to facilitate administrative issues related to the research.

6. Research projects submitted for approval shall be administered by staff of the University. Outside research projects must include staff of the University serving as coordinator, consultant or co-researcher.

7. Cooperation among Institutions which may or may not have a Committee on Ethical Research on Humans and the transfer of rights to oversee research projects to the University Committee on Ethical Research on Humans, as well as training on the ethical issues concerning research on humans

7.1 An Institution not having a Committee on Ethical Research on Humans may request the cooperation of an Institution which has one on the same campus or seek the cooperation of the University Committee on Ethical Research on Humans by having the Head of the Institution or his/her representative send a memorandum of transfer. In the case of transferring the rights to the University Committee on Ethical Research on Humans, the Head of the Institution shall submit a memorandum of transfer to the Vice President of Research and Academics

7.2 In the case of a multi-centered study, with the cooperation of various Institutions within Mahidol University, there may be a transfer of rights to any one of the Committees on Ethical Research on Humans which will monitor the research project, or else

transfer the rights to the University Committee on Ethical Research on Humans in order to save time and resources and so have all of the Institutions start their work simultaneously

7.3 Providing knowledge and training on the ethical issues concerning research on humans at the University

7.3.1 Providing knowledge for researchers

Providing knowledge concerning the ethics of research on humans is a tool to develop a sense of consciousness and awareness for researchers in order to protect the rights and welfare of research participants within the project for whom they are responsible. This will ensure the community that those who participate in research projects will be appropriately looked after. The Committee on Ethical Research on Humans shall manage training sessions at least once a year on the ethics of research on humans for Institutional staff and others who are interested

7.3.2 Providing knowledge for the Committees on Ethical Research on Humans

The Committees on Ethical Research on Humans shall have knowledge regarding the ethics of research on humans according to international standards and should follow the progress of these principles continuously in order to always be up-to-date and in line with new types of development in research. Knowledge on ethical issues that shall be provided to the committees are as follows

- Orientation for new committees
- Academic seminars for the Committees on Ethical Research on Humans that may be conducted on an institutional basis or jointly with other organizations, such as the Association of Ethical Research on Humans of Thailand
- Provide books, textbooks or academic journals for the Committees on Ethical Research on Humans to further increase their knowledge
- Prepare guidelines for the Committees on Ethical Research on Humans, specifying ethical criteria of an international standard and the functions of the Committees, including administrative processes for research projects submitted to the Committees.

8. There shall be quality assurance for administration in line with the developmental policies of Mahidol University by establishing a working committee, consisting of representatives from the Committees on Ethical Research on Humans registered with the University, which will stipulate all policies and quality assurance plans.