

Mahidol University Announcement On Guidelines for Conducting Non-Human Subjects Research, B.E.2565 (2022)

As deemed appropriate, this announcement is issued to establish clear guidelines for conducting and identifying characteristics of non-human subjects research, for which a review is not required by the university's Institutional Review Board (IRB).

By virtue of Article 34 (1) of Mahidol University Act, B.E.2550 (2007), the President establishes the announcement as follows:

Article 1 Any research possessing the following characteristics is considered non-human subjects research and therefore does not require IRB review.

- 1.1 The research does not fall within the scope of studies that require IRB review and approval as outlined in the Mahidol University Announcement on Policy on Conducting Research with Humans.
- 1.2 The research does not involve systematic data collection or analysis designed to develop generalizable knowledge according to the disciplines of social sciences, behavioral sciences, biomedical sciences, or epidemiology or does not involve individuals in one of the following manners.
- (1) Researchers conduct manipulations, interventions, observations, or other interactions with research participants whether directly or indirectly by altering the environment.
- (2) Researchers obtain personal data that may enable identification of individuals from medical or other records. This includes the preparation and use of identifiable biological specimens in research, such as human specimens including organs, blood, skin, hair, nails, urine, saliva, secretion, cells, tissue, protein, or DNA, which may be obtained from patients during diagnosis or treatment processes, regardless of whether they are intended for disposal or have already been disposed of, or those may be collected from deceased individuals during autopsies, organ donations, or other processes.

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Article 2 In case the principal investigators wish to check whether their research is qualified as non-human subjects research, they can proceed with a self-assessment of the research via the Mahidol University Center of Ethical Reinforcement for Research website (https://sp.mahidol.ac.th/th/ethics-human/assessment.html). If the research is assessed as non-human subjects research, the investigators may print out the completed assessment form as a reference. Principal investigators who are university staff may sign the assessment form themselves. For student investigators, they may complete the assessment form, but must have their forms signed by their major advisor/supervisor who are university staff.

Article 3 After the completion of the self-assessment form, should researchers require further clarification regarding the assessment, they may contact or seek advice from their IRB at their Faculty/College/Institute or the Mahidol University Central IRB.

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President of Mahidol University