



APPROVED BY

ISM University of Management and Economics, UAB
President's Order of November 30, 2022
No. 2022/01-07-72

OPERATIONAL REGULATIONS OF THE INSTITUTIONAL REVIEW BOARD

1. General provisions

- 1.1. The purpose of the Institutional Review Board (hereinafter the IRB) is to grant an ethical approval of research planned by members of community at ISM University of Management and Economics, UAB (hereinafter ISM University) before the research is conducted.
- 1.2. The composition of the IRB shall be approved by the President of ISM University.
- 1.3. The Operational regulations (hereinafter the Regulations) of the IRB shall be approved by the President of ISM University and shall become effective from the day of signing.
- 1.4. The Chairperson of the IRB shall be accountable for the operations of the IRB to the President of ISM University.
- 1.5. All information on the intended research provided to the IRB for ethical evaluation shall be held confidential by its members.
- 1.6. The IRB Regulations shall be made public on the website of the ISM University in Lithuanian as well as in English.

2. IRB Functions

- 2.1. The main functions of the IRB are as follows:
 - 2.1.1. to evaluate the compliance of research to be conducted by the faculty, staff and doctoral students (hereinafter members) of ISM University to the general principles of research ethics and integrity and grant an ethical approval of it;
 - 2.1.2. to promote research ethics and integrity among members of ISM University and consult its members on related issues.
- 2.2. Research evaluation by IRB is aimed at assuring the following:
 - 2.2.1. respect for research participant dignity, welfare and rights and to mitigate the risks of causing any damage to research participants;
 - 2.2.2. adherence to open science practices where possible and the requirements of (personal) data management regulations;
 - 2.2.3. compliance with the values and principles of the research ethics.
- 2.3. IRB evaluation and approval applies to 1) PhD research, 2) independent and funded – by the state, agencies, or private companies – scientific and applied research projects (hereinafter, research) carried out in Lithuania by members of ISM University. Provided that an approval is needed for research to be conducted by bachelor or master students, an application shall be submitted by their thesis advisor.
- 2.4. The IRB shall only evaluate research involving human subjects (hereinafter, research participants), personal data, and/or environmental concerns.
- 2.5. Biomedical research or research related to animal subjects are out of scope of the responsibilities of the IRB. Members of ISM University who intend to conduct such research shall seek approval from respective bodies in Lithuania (Lithuanian Bioethics Committee regarding biomedical research and State Food and Veterinary Service regarding research including animals).

2.6. The activities of the IRB shall be based on the principles of research ethics and shall follow the regulatory requirements for research conduct in Lithuania, the guidelines of the Ombudsperson for Academic Ethics and Procedures of the Republic of Lithuania, and the good practice and codes of conduct of international organisations such as – but not limited to – the European Code of Conduct for Research Integrity, ESOMAR Code of Ethics, etc.

3. IRB formation and management

3.1. The IRB shall consist of at least six members representing the main research groups and related fields of activity at ISM University with the following experience:

3.1.1. at least two faculty members having no less than 10 years of experience of conducting scholarly research, with one of them also having experience of working on the editorial board of an academic journal;

3.1.2. at least two faculty members having no less than 5 years of experience of conducting scholarly research;

3.1.3. at least one academic member having at least 1 year of academic research experience, and at least 2 years of work experience in business;

3.1.4. a lawyer or other staff member of ISM University having no less than 2 years of work experience in data protection.

3.2. The IRB members have to be of irreproachable reputation and shall sign the commitment to confidentiality that they shall abide to for a period of 5 years upon the completion of their term. The confidentiality of personal data shall be protected for an indefinite period.

3.3. The academic members of the IRB shall be elected for a three-year term. After two years at least one new academic member meeting the above requirements shall be elected for a three-year term to assure consistency in the IRB activities after the change of its composition upon the expiration of the term of service of the majority of its members.

3.4. The IRB members shall elect a Chairperson and a Deputy Chairperson for the period of one academic year during the first meeting of the newly elected IRB and consequently at the first IRB meeting in the following academic years.

3.5. The IRB meetings shall be chaired by the Chairperson or the Deputy Chairperson. Provided the Chairperson and the Deputy Chairperson may not attend a meeting, the IRB members shall elect an Acting Chair of the meeting.

3.6. IRB meetings shall be organised as needed, i.e. upon the receipt of an application from a member of ISM University to review their research, during the academic year, i.e. from September to June. The Chairperson or the Deputy Chairperson of the IRB shall convene an IRB meeting by sending an e-mail with the agenda of the planned meeting to all IRB members.

3.7. The role of the IRB secretary shall be rotated and performed by an IRB member elected by the IRB for a five-month period.

3.8. Provided a member of the IRB resigns or is withdrawn by the President of ISM University before their term expires, a new member shall be elected as specified in article 3.1 of the Regulations to replace them for the remainder of the IRB term.

3.9. IRB members who have a potential conflict of interest in the research project submitted for the IRB evaluation shall inform the IRB Chairperson or Deputy Chairperson in writing immediately and recuse themselves from the evaluation. Provided the IRB Chairperson encounters a conflict of interest, he/she shall inform the Deputy Chairperson in writing,



recuse himself/herself from the evaluation and delegate the meeting chairing function to the Deputy Chairperson.

4. IRB work procedures and decision-making

- 4.1. Members of ISM University who intend to start a research project as specified in 2.3. and 2.5. shall submit an application to the IRB prior to initiating the research. The application shall be submitted by the principal investigator. The application and information on its preparation and submission shall be available on the E-Learning platform.
- 4.2. The IRB shall evaluate compliance of the research with the ethical standards only before the research is conducted, with the exception of longitudinal and multi-study research that was started before the IRB began its activities. In the latter case, the IRB shall only evaluate the compliance of the new research stages.
- 4.3. Upon receiving an application, the IRB Chairperson shall convene a meeting within 15-20 working days to evaluate the compliance of the intended research with research ethics. The meeting shall be considered valid if more than half of the IRB members are present. Meetings shall be closed and may be organised face-to-face, online or in a hybrid mode. Principal investigators of the submitted applications shall be invited to the meeting if additional information is needed to make the decision or shall request participation upon their own initiative in writing prior to the respective meeting.
- 4.4. The IRB has the right to approve, reject, and/or request amendments in the intended research plan in line with the applicable ethical and legal requirements.
- 4.5. The IRB shall take the following issues into consideration in their research evaluation:
 - 4.5.1. potential risk of intended research to research participants and intended measures to mitigate it;
 - 4.5.2. if participation in the intended research is voluntary and based on the informed consent;
 - 4.5.3. if the needs and interests of research participants are respected and protected if they include underaged and/or persons from vulnerable groups;
 - 4.5.4. adherence to the principles of confidentiality and data protection;
 - 4.5.5. the use of payments, reimbursement of expenses or any other benefits or incentives in the intended research and their justification.
- 4.6. IRB decisions on research approval shall be made based on consensus or by vote, if needed. All IRB members shall have equal voting rights; however, in case of an equal number of votes, the voice of the IRB Chairperson shall be decisive.
- 4.7. The IRB shall make the decision on research compliance with ethics and inform the applicants about their decision no later than in 20 working days since the IRB meeting.
- 4.8. Provided the IRB lack competence to evaluate a specific research project, they shall seek advice from and collaborate with other members of ISM University and /or external bodies. Non-IRB members shall perform only an advisory role and shall have no voting right.
- 4.9. If the IRB do not approve an application and raise some concerns and/or recommends some adjustments, the applicant(s) shall amend their research plan as recommended and resubmit the application for re-evaluation, or provide a reasoned argument in case they disagree with the IRB recommendations, or inform the IRB of their decision not to conduct the intended research.