Rules of procedure of the Ethical Review Board
of the faculty of Mathematics and Computer Science, Saarland University

The rules of procedure supplement the terms of reference of the ethical review board and governs the procedures.

§1 Duties

The board becomes active on request of a scientist of the faculty.

The ethical review board evaluates and, if necessary, takes a position on ethical aspects of planned research projects involving human subjects and personal data. The responsibility of the scientist in charge remains untouched.
The ethical review board evaluates in particular, if

(1) all measures to minimize the risks for the test person and the misuse of personal data have been taken,
(2) the ratio between benefits and risks of the project is appropriate,
(3) the implementation of the project meets the relevant legal requirements, especially the provision on data protection,
(4) the proposals to the board, if necessary, contain information on
    - the aim of the project,
    - the kind of the used personal data, how it was collected and how it was processed and stored.
    - For projects involving human subjects:
        1. the type and number of test persons, as well as the criteria for their selection
        2. the steps of the examination procedure
        3. burdens and risks for the test persons, including potential consequences and measures to prevent negative effects
        4. rules on how to inform test persons on the test process, which fully, truthfully and understandably for the test person inform about the goals and the process of the test
        5. rules on test person ‘s consenting to his/her participation in the test
        6. a test person's options to refuse his/her participation or to withdraw their consent, in case of test persons with limited decision-making-ability (such as children, legal incapacity): regulations regarding the possibility of agreement to participation in the test via legal guardians or custodians, where required included insurance coverage,
        7. type of data collection (in particular audio and video recording and log files) and data storage in the light of data anonymization.

The ethical review boards and its members are independent concerning the safeguarding of their duties and not bound by any directions. They are only responsible to their conscience.

§2 Filing a proposal

(1) The evaluation of a research project takes place upon request of the scientist in charge or the dean of the faculty of Mathematics and Computer Science
(2) The proposal is processed only if it has not yet been submitted for evaluation at any other ethical review board
(3) Documents relevant for the ethical vote must be submitted electronically (as a PDF-file if possible) to the board's chairperson by the applicant/s
(4) Rejections of proposals are ruled on a case-by-case basis.

§3 Evaluation process

(1) The ethical review board takes positions on the basis of votes of at least three board members.
(2) Members who contribute to the research project or whose interests are affected in such a way that they may be biased are excluded from the evaluation and decision-making process.
(3) The ethical review board regularly decides using electronic file circulation. Every member may demand an oral consultation at any time.
(4) The chairperson of the board or the board as a whole may demand the applicant to explain the project verbally or may demand additional documents, information or justifications.
(5) If there are significant concerns against a proposal, the applicant may be asked to hand in a revised proposal
(6) The applicant may be heard by the board before taking a position. If the applicant wishes to be heard, he/she must be heard.
(7) The decision of the ethical review board must be communicated to the applicant in written form. Rejections, conditions and recommendations for changes in the project must be justified in writing
(8) If a proposal is rejected for ethical reasons, the applicant may present counterarguments and demand a renewed decision of the board
(9) Decisions of the board require a simple majority of its members. If a decision is made, it is a decision of the board as a whole
(10) The board may authorize the chairperson to decide by himself / herself in special cases that need to be defined closer. He / She must inform the board as soon as possible about his / her decision
(11) Obvious cases may be evaluated in a simplified process, such as using a checklist
(12) Multicentre-studies which have already been evaluated by another board may be evaluated by the chairperson. The board must be informed and in case of doubts be addressed.

§4 Confidentiality of the ethical review

(1) Sessions of the ethical review board are not open to the public. All decisions have to be recorded in a protocol. Both, the subject of the review and the board's ethical votes must be kept confidential. Members of the board are sworn to secrecy. The same applies to consulted knowledgeable experts. Individual votes are kept confidential as well.

(2) The members of the ethical review board must be instructed on their secrecy at the beginning of their activity.
(3) Votes of the board, application documents, meeting protocols, amendments, intermediate and final reports, correspondence etc. must be archived.
(4) When archiving applicant documents, the data protection must be respected

§5 Votes of the board

(1) Votes of the board on applications in accordance with §2, section 1, No. 1 are either:
   a. “There are no ethical concerns against the implementation of the research project”, or
   b. “There are no ethical concerns against the implementation of the research project, if requirements to be determined are fulfilled”, or
   c. “There are ethical concerns against the implementation of the research project”.
(2) The supporting or rejecting votes must be communicated to the applicant in written form. Tips, advice and recommendations may be added to the votes. Rejecting votes must be justified in written form.
(3) Research projects are evaluated on a case-by-case basis. Votes may be expanded to one or more additional research projects in a simplified process by a “modifying decision”.
(4) The applicant has to determine the time frame a vote is applied for.
(5) The ethical review board documents the applications and the decisions. Written documents are archived for ten years.