



## CODE of ethics for scientific research with human participants

### Preamble

Transilvania University of Braşov, part of the national research and development system, is responsible, through all members of the academic community, for the observance of ethical values and norms in scientific research, technological development and innovation.

The research, development and innovation code of ethics defines principles and rules of conduct and establishes procedures regarding the design, organization, conduction and completion of scientific research activities with human participants in the fields of social sciences and humanities. This Code is in compliance with and is supplemented by the provisions of the Code of Academic Ethics.

The content of this code of ethics for scientific research with human participants has been drafted in accordance with the provisions of the following normative acts:

Law no. 1/2011, the National Education Law, with subsequent amendments and additions;

Law no. 206/2004, regarding good conduct in scientific research, technological development and innovation, with subsequent amendments and additions;

Ministerial order no. 211/2017 regarding the approval of the Regulation on the organization and operation of the National Ethics Council of Scientific Research, Technological Development and Innovation – CNECSDTI, as well as its nominal composition;

General Regulation on the Protection of Personal Data of the European Parliament (GDPR), 2016/679;

Law no. 363/2018 on the protection of natural persons with regard to the processing of personal data;

European Code of Conduct for Research Integrity, 2017;

European Charter for Researchers and Code of Conduct for the Recruitment of Researchers;

Charter of Transilvania University in Braşov.

### Chapter I. General provisions

**Art. 1** A human participant/subject is any living individual on whom research is carried out in order to obtain data through an intervention, an interaction with the individual or private information regarding his identity.

**Art. 2** The following are not considered research with human participants:

- a) research concerning deceased individuals;
- b) research that collects information that does not target opinions, attitudes, behaviours, emotions, etc.;
- c) audit or journalism activities;
- d) mutually agreed upon research carried out in stable educational environments and which is based on regular educational practices;
- e) research involving the investigation, interview or observation of public behaviour, provided that any disclosure of information or their identification outside the context of the research does not expose the participants to risk, does not determine their criminal or civil liability and does not damage their social, professional, or financial status or their reputation;

- f) secondary analysis of public data, provided that they are public or anonymized so that the subjects cannot be identified;
- g) staff performance evaluation studies for internal institutional use or audit studies;
- h) oral stories, memories of certain events.

**Art. 3** (1) Research carried out on children, regardless of their type, will be subjected to the full review of the research ethics committee.

(2) The study of private documents belonging to a deceased person will be conducted with the consent of morally authorized persons.

(3) For the review of official documents, if the documents are not public, the consent of the institutions involved will be requested.

**Art. 4.** Data about participants that reveal the racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic or biometric data, data on health, sex life or sexual orientation of natural persons are considered sensitive data. The processing of this data is done in compliance with the applicable norms and regulations.

## **Chapter II. Ethical principles of scientific research activity**

**Art. 5** Protection of participants.

The researcher will protect the personal, social, financial, organizational or political status of research participants, will do no harm and will ensure the rights of all those with whom they interact in carrying out the research.

**Art. 6** Promoting the well-being of the participants.

The researcher will work for the benefit of the participants, establish trusting relationships with those they work with, by following the standards of professional conduct, being aware of their professional and scientific responsibilities for society and for the specific communities in which they work.

**Art. 7** Promotion of accuracy, honesty and truth.

Researchers will not deceive, engage in fraud or intentionally misrepresent the facts and data they refer to and conclusions they publish or provide to participants.

**Art. 8** Fairness and awareness of competence limits

The researcher shall not go beyond the limits of their competence, shall not use tools or methods for which they are not qualified, and shall avoid that his expertise lead to unfair practices.

**Art. 9** Respect for the dignity and value of people, the right to privacy, confidentiality and self-determination.

The researcher will honour cultural, individual and role differences, including age, gender, race, ethnicity, cultural background, national origin, religion, sexual orientation, disability, language and socio-economic status when working with members of these groups.

## **Chapter III. The norms of conduct and violation**

**Art. 10** The norms of conduct regarding research with human participants apply to:

- a) scientific activity, from its design to its completion;
- b) communication activity, publication of research and development results;
- c) patents, protection of industrial designs and models (in accordance with Law no. 129/1992, republished), copyright and related rights (in accordance with Law no. 8/1996 with subsequent amendments and additions);

d) institutional evaluation and monitoring of research and development activities from the perspective of their compliance with ethical norms.

**Art. 11 (1) Violations mentioned in art. 310, Law 1/2011, are considered deviations from the norms of conduct in scientific research, as follows:**

- a) plagiarizing the research results or publications of other authors;
  - b) fabricating results or replacing results with fictitious data;
  - c) using false information in grant or funding applications;
- (2) Participating by association in violations of good conduct norms determines ethical responsibility, according to art. 2.1(6) of Law 206/2004, with subsequent amendments and additions.
- (3) In research with human participants, deviations from the norms of conduct include, in addition to serious deviations, various forms of discrimination, non-disclosure of conflicts of interest, breaches of confidentiality, abuse of authority, obstruction of the research and development activity, obstruction of the activity of an ethics Committee or a Committee conducting assessments in the field of research and development or the National Council of Ethics, as well as non-compliance with legal provisions and procedures, in accordance with applicable regulations.

#### **Chapter IV. The organization and functioning of the ethics committee in Social Sciences and Humanities research**

**Art. 12** The Committee for Ethical Endorsement in Scientific Research with Human Participants (CECS within Transilvania University of Braşov is established alongside the Council for Scientific Research. The Committee is proposed by the Council for Scientific Research, approved by the University's Administrative Council, validated by the Senate and appointed by order of the Rector.

**Art. 13** The Committee is comprised of a president, a vice-president, a secretary and six members, appointed for a for-year term.

- a) The Ethics Committee is comprised of persons with competence in assessing, from an ethical perspective, the acceptability of research in social sciences and humanities.
- b) In reviewing a request for ethical endorsement, the Committee will operate with a president, a secretary and three members. The members will be appointed by the Committee president, after a preliminary review of the application.

**Art. 14** The duties of the Committee for Ethical Endorsement in Scientific Research with Human Participants are as follows:

- a) to decide, within 5 working days from the receipt of an endorsement request submitted by a member of the academic community, whether it will be subjected to a full analysis; if the Committee decides that the study is not to be considered "research with human participants", a notice to stop the review process is issued;
- b) to review the research project proposal from an ethical perspective, to endorse it, reject it or to request changes to the proposed research in order for it to comply with ethical norms; for projects that participate in national or international competitions, the endorsement request will be made at least 30 days before the submission of the project, and if the committee recommends changes, an answer will be provided within 10 days after receiving the change recommendations;
- c) if the project is endorsed, to carry out continuous evaluations of the research and review any changes in ethical conduct that may appear along the way;
- d) to suspend the endorsement if a violation of research ethics norms is found;
- e) to analyse the forms for obtaining informed consent and the procedures used to obtain it;
- f) to analyse reports/self-reports and prepare analysis reports;

- g) to ensure the endorsement of the notification analysis report by the legal advisor of the institution;
- h) to document its own activity and keep all documents in safe conditions, to be made accessible according to legal regulations.

**Art. 15 (1).** The Committee for Ethical Endorsement in Scientific Research with Human Participants within Transilvania University of Braşov endorses a research/study proposal if the following conditions and met:

- a) the risk to participants is minimal;
- b) the risk is acceptable in relation to the expected benefits;
- c) the selection of participants is fair;
- d) informed, personal, or parental consent is obtained appropriately;
- e) protection of personal data and confidentiality is ensured;
- f) the processing of participants' personal data, in particular sensitive personal data, is subject to the existence of the appropriate safeguards referred to in the request for informed consent;
- g) there are special rules in place for research involving children, persons with impaired judgement or disadvantaged persons;
- (h) the institution/organisation has given its consent for carrying out the research, where appropriate.

(2) The Committee may review and ethically endorse a scientific research whose main researcher is from another university/research structure/entity, provided that there is a documented partnership with teaching staff within Transilvania University. A Transilvania University academic will sign the documents submitted to the Committee together with the main researcher and will be jointly responsible with the main researcher for complying with the ethical norms.

(3) The Committee may reject a study/research proposal, providing the reasons for its decision and indicating the necessary changes so that the request can be submitted for further consideration.

**Art. 16** The Committee may organise training courses on the subject of ethics in the field of research with human participants for teachers and researchers.

**Art. 17 (1)** In carrying out research for the completion of bachelor's and master's studies, the adherence to ethical norms shall be ensured by the student and the supervising professor. This research is not to be subjected to the review of the research ethics committee.

(2) The papers written for the completion of master's degree studies may be subjected to an ethics review if they are considered for publication, in compliance with all the rules and procedures defined by the Code. In this case, the main researcher is the student and the academic supervisor will ensure that the student complies with the ethical norms. The supervising professor will sign the documents submitted to the committee together with the student.

(3) For endorsing research carried out by PhD students, the supervisor will sign the documents submitted for ethical endorsement together with the student.

**Art. 18** In order to obtain and maintain the endorsement of the committee, the researcher is required to:

- a) submit a request to the ethics committee;
- b) fill out the research endorsement form, meeting all the requirements of the ethics committee;
- c) submit the documents for requesting the ethical endorsement to the University Registry Office on paper and then send them to the Commission's email address, in pdf;
- d) evaluate the degree of acceptability of the research from an ethical point of view and the degree of risk of the research for the human participants, according to the self-assessment sheet provided by the Committee;
- e) achieve a clear and fair agreement with human participants, prior to their participation, regarding the obligations and responsibilities of each party; for projects submitted to apply for public funding, agreements are made after obtaining the grant, but before starting the research;

- f) draft the informed consent form and draft the team's confidentiality agreement, if applicable, bring them to the attention of those involved and make sure they are signed;
- g) ensure that the informed consent form sent to the Commission is an exact copy of the form that will be presented to the participants/parents/guardians, as the case may be;
- h) present all the documents regarding research ethics when submitting the request; if the committee requires other documents, they will be submitted within the deadline given by the committee so as to allow the review to be carried out efficiently;
- i) in the case of research that includes an intervention/experiment with human participants, it will present, along with the tools used in the pre-test and post-test, a brief description of all intervention sessions;
- j) for the tools used, they will mention, under their own responsibility, if they are developed by the research team, are free to use, are used with the consent of the authors or require obtaining a license;
- k) appear, at the commission's request, to provide additional clarifications to the information provided in the approval form;
- l) make any changes regarding research ethics requested by the committee;
- m) present to the committee, if appropriate, and follow all the steps of the endorsement process for any changes in research ethics that may have occurred during the course of the research;
- n) abide by all promises and commitments included in the confidentiality agreement and informed consent forms;
- o) carry out an ethical training of team members and participants;
- p) for projects that are submitted to obtain public funding, the activities from sub-points b, c, h, m and n shall be carried out only after obtaining the grant/project.

**Art. 19** Committee members maintain confidentiality of the work of the Committee and the data provided by the researchers and recognize the Main Researcher's intellectual property rights over the research methodology and sign an internal document to this effect.

**Art. 20** Any report of a research and development ethical conduct violation involving activities with human participants shall be made in writing and shall be accompanied by supporting documentation. The report shall include the identification details of the person making the complaint, the person who is the subject of the report and the allegations. The report shall be addressed to the Rector.

**Art. 21** In analysing reports and self-reports, the committee shall carry out the following activities:

- a) records the report;
- b) establishes the dates for conducting the examination and the persons asked to provide information;
- c) summons the persons concerned;
- d) examines the information;
- e) drafts the analysis report and subjects it to the Legal Adviser's approval;
- f) communicates the report to the persons concerned;
- g) posts the report on the University's intranet page.

**Art. 22** The forms used by the committee are as follows and may be revised periodically by the committee:

- a) endorsement request form for research projects with human participants;
- b) endorsement form for research projects with human participants;
- c) interim and final monitoring form for research involving human participants;
- d) endorsement withdrawing form for research involving human participants;
- e) informed consent form for participants, parents or guardians (for minor, vulnerable, impaired participants);
- f) form granting consent by the institution/company to conduct the research;
- g) agreement to keep the research data confidential between the team and the coordinator;

- h) public report form for violation report analysis;
- i) form for recording the work of the committee.

**Art. 23** Appeals against the Committee's decisions shall be addressed to the University Ethics and Professional Conduct Committee. Appeals may be submitted within three working days after the decision has been communicated to the applicant.

This Code was discussed and approved at the meeting of the Senate of Transilvania University of Brasov on June 14, 2023.

Prof. Dr. Eng. Mircea Horia ȚIEREAN,  
President of the Senate of Transilvania University of Braşov

