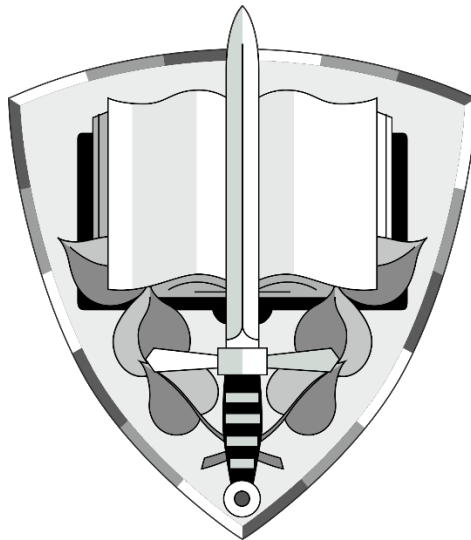


Ref. No. MoD 669056/2023-2994

Approved by:
Brigadier General Prof. RNDr. Zuzana Kročová, Ph.D.,
Rector

Brno, 13 September 2023

signed electronically



**MEASURE OF THE RECTOR
OF THE UNIVERSITY OF DEFENCE
No. 15/2023
ETHICS COMMISSION OF THE UNIVERSITY OF DEFENSE**

Article 1
Subject Matter

Based on Article 6 (3) of the Organisational Regulations of the University of Defence¹ ("the Organisational Regulations"), this Measure sets out the composition and method of establishing the Ethics Commission of the University of Defence ("the Commission") and the code of its procedure.

Article 2
Activities of the Commission

- (1) The subject matter competence of the Commission is under Article 6 (1) of the Organisational Regulations.
- (2) Once a year, the Commission prepares a report on its activities, which is published in the public section of the website of the University of Defence ("the University"), and the data contained therein are generally included in the University's annual report.

Article 3
Composition and Method of Setting up the Commission

- (1) The Commission is composed of twelve members.
- (2) The members of the Commission are appointed by the Rector from among academic staff, other employees and students of the University on the basis of a proposal from the heads of the basic organisational units of the University² and removed by the Rector so that the above-mentioned groups of persons are represented on the Commission.
- (3) A person may be appointed as a member of the Commission only with his or her previous consent.
- (4) The Rector submits the intention to appoint or remove a member of the Commission to the Academic Senate of the University of Defence for its evaluation.
- (5) Membership of the Commission is irreplaceable.
- (6) Membership in the Commission is incompatible with the position of rector, vice-rector, bursar, deputy rector, chancellor, dean, vice-dean, secretary of the faculty, director of a university institute and director of a centre.
- (7) The term of office of a member of the Commission is three years and starts on the date on which the Rector appoints him or her to office. A person may be reappointed as a member of the Commission.
- (8) Membership of the Commission ceases
 - a) at the end of the term of office,
 - b) by appeal,
 - c) by renouncing membership,
 - d) by death or declaration of death,
 - e) by restriction of legal capacity,

¹ Measure of the Rector of the University of Defence No. 21/2021 – Organisational Regulations of the University of Defence.

² Article 7 (1) Measure of the Rector of the University of Defence No.21/2021 – Organisational Regulations of the University of Defence.

- f) by termination of employment or service with the University,
- g) by ending up belonging to the part of the academic community of the University for which he or she was appointed.

Article 4
Chair of the Commission

- (1) The Commission elects its Chair by public vote. A supermajority vote of all members of the Commission is required to elect the Chair of the Commission.
- (2) Chair of the Commission
 - a) represents the Commission externally,
 - b) convenes the Commission,
 - c) chairs the commission meeting,
 - d) discusses with the submitters the Commission's views on matters submitted to the Commission,
 - e) informs the Rector of the submissions made under Article 14 and of the Commission's opinions on the submissions and applications before they are forwarded to the submitters and published,
 - f) signs the opinions of the Commission.
- (3) In the absence of the Chair of the Commission, he/she is represented by a member of the Commission designated by him/her to the extent specified by him/her.
- (4) If there is no Chair of the Commission, a member of the Commission appointed by Rector acts as Chair of the Commission until the Chair of the Commission is elected.

Article 5
Rights and Obligations of the Members of the Commission

- (1) A member of the Commission has the right
 - a) to decide in all cases where the Commission decides by vote,
 - b) to make initiative proposals for the inclusion of items on the agenda of the Commission, to make suggestions and comments,
 - c) to speak on the items on the agenda of the Commission meeting and to express his/her views and make suggestions and comments on them,
 - d) to consult the relevant documents needed to prepare for the Commission's deliberations,
 - e) on the basis of the instruction of the Chair of the Commission or the conclusions of the meeting of the Commission, to require cooperation from appropriate University authorities and staff to fulfill the scope of the Commission.
- (2) A member of the Commission is obliged
 - a) to attend and prepare for Commission meetings, to study the materials on the items on the Commission's agenda, to assess them responsibly, to express their own opinions and to actively contribute to the resolution of these items,
 - b) to properly apologise to the Chair of the Commission or the Secretary of the Commission if he/she is unable to attend a Commission meeting,

- c) c) to immediately notify the Chair of the Commission of his or her bias on the agenda item under discussion and abstain from voting on the opinion on that item,
- d) d) to maintain the confidentiality of all facts of which he/she has become aware in connection with the activities of the Commission.

Article 6
Secretary of the Commission

- (1) Organisational and administrative matters of the Commission are handled by the Secretary of the Commission appointed by the Rector on the proposal of the Chair of the Commission.
- (2) The Secretary is not a member of the Commission.
- (3) Secretary of the Commission
 - a) in cooperation with the Chair of the Commission, compiles background materials for the Commission's meetings,
 - b) ensures the administrative and organisational preparation of the Commission meetings, timely sending of invitations and supporting materials to the Commission members for individual Commission meetings,
 - c) administratively ensures the conduct of the Commission's meetings,
 - d) takes minutes of the proceedings of the Commission meetings, draws up written resolutions of the Commission adopted at the Commission meetings according to the instructions of the Chair of the Commission,
 - e) according to the instructions of the Chair of the Commission, draws up in writing the opinions of the Commission adopted at the meetings of the Commission,
 - f) publishes the opinions of the Commission in the manner prescribed,
 - g) keeps a record of relevant Commission documents (in the ESSS system),
 - h) performs other tasks related to the activities of the Commission as directed by the Chair of the Commission.
- (4) The provisions of Article 5 (2) and the provisions of Article 8 apply mutatis mutandis to the Secretary of the Commission.

Article 7
Working Groups, Participation of Independent Experts and Expert Opinions

Working groups of at least three Commission members are set up for consideration of each type of submission and application. A member of the Commission and, with the consent of all members of the Commission, other persons may be members of a working group of the Commission. A member of the Commission may be a member of no more than two working groups.

- (1) The Chair and other members of the Commission's working group are appointed by the Commission.
- (2) If the complexity of the matter under discussion makes it necessary, the Chair of Commission may, with the consent of the Rector, invite an independent expert to the meeting of the Commission or a working group of the Commission or request the preparation of a written expert opinion.

- (3) The costs associated with the participation of independent experts and the preparation of written expert reports are borne by the University.

Article 8 Confidentiality

- (1) A member of the Commission confirms his/her obligation to maintain the confidentiality of all facts of which he/she has become aware in connection with the activities of the Commission by signing the relevant declaration without undue delay after his/her appointment.
- (2) The obligation of confidentiality is agreed upon with any person who is a member of a Commission working group, an invited independent expert, or who prepares an expert opinion for the Commission.
- (3) In justified cases, the Rector is entitled to relieve a given person of the obligation of confidentiality on the proposal of the Chair of the Commission.

Article 9 Meetings of the Commission

- (1) Meetings of the Commission are closed to the public.
- (2) The Commission meets as required, but at least once per calendar year.
- (3) The Commission meets on the basis of
 - a) the decision of the Chair of the Commission, or
 - b) a written request for a meeting of the Commission submitted by at least two members of the Commission stating the proposed agenda.
- (4) The Commission has a quorum if at least seven members of the Commission are present.

Article 10 Convening of Meetings of the Commission

- (1) A meeting of the Commission is convened by the Chair of the Commission.
- (2) The Chair of the Commission convenes a meeting of the Commission within 15 working days of receipt of the submission referred to in Article 14 (1), the request referred to in Article 15 (1) or the written request referred to in Article 9 (3)(b). The Chair of the Commission informs the Rector of the date of the meeting of the Commission.
- (3) The invitation to the Commission meeting is sent by the Secretary of the Commission as instructed by the Chair of the Commission.
- (4) The invitation to the Commission meeting, in paper or electronic form, must include the date and place of the Commission meeting and the proposed agenda and must be delivered to the Commission member at least 5 working days prior to the Commission meeting. Supporting documents on the matters to be discussed at the Commission meeting are, where this is not contrary to the legislation on the protection of classified information³, sent to the members of the Commission in paper or electronic form, within the time limit referred to in the first sentence.

³ Act No. 412/2005 Sb., on the Protection of Classified Information and Security Clearance, as amended.

- (5) If a member of the Commission is unable to attend a meeting of the Commission, he/she notifies the Chair of the Commission or the Secretary of the Commission without undue delay.
- (6) The Chair of the Commission may invite other persons to the Commission meeting to discuss selected issues.

Article 11
Conduct of the Meetings of the Commission

- (1) Before the Commission meeting commences, the Secretary of the Commission verifies that the Commission is quorate and reports the result to the Chair of the Commission. If the Commission is not quorate, the Chair of the Commission sets a new date for a meeting of the Commission with the same agenda.
- (2) The Chair of the Commission chairs the meetings of the Commission according to the approved agenda.
- (3) The Commission discusses the individual items on the approved agenda in such a way that, after the introductory word on the agenda item under discussion, the Chair of the Commission opens the debate.
- (4) The Commission takes a position on the submissions made under Article 14 and the requests under Article 15, which are discussed in the Commission.
- (5) The Secretary of the Commission takes minutes of the conduct of the Commission meeting ("the minutes"), which are signed by the Chair of the Commission and the Secretary of the Commission.

Article 12
Voting on Proposals

- (1) Each proposal is put to the vote at a meeting of the Commission in a public manner.
- (2) A submitted proposal is approved if at least seven members of the Commission vote in favour of it.
- (3) At the request of a member of the Commission, the minutes must state his or her dissenting opinion or disagreement with the resolution adopted, together with a brief justification.
- (4) In the event that this is necessary for time reasons or due to the relative simplicity and clarity of the documentation and the requested decision, the Chair of the Commission may, outside the Commission meeting, submit in writing to the other members of the Commission a draft resolution to be adopted ("the written vote"). The draft resolution must include a time limit for the members of the Commission to express their agreement or disagreement in writing. If a member of the Commission fails to express his or her written opinion on the draft resolution within the time limit, he or she is deemed to disagree with the draft resolution. The approval of at least seven members of the Commission is required for the adoption of a resolution by written vote. The result of the voting by written vote is immediately communicated by the Chair of the Commission to all members of the Commission. Minutes of the voting by written vote are taken and signed by the Chair of the Commission and the Secretary of the Commission.
- (5) Voting by written vote, pursuant to paragraph 4, is excluded on motions for resolutions containing sensitive personal data.

- (6) If at least three members of the Commission disagree with the adoption of the draft resolution by written vote no later than the deadline set for expressing their agreement or disagreement with the draft resolution in writing, the results of the vote are not taken into account, and the draft resolution is voted on at the Commission meeting.

Article 13

Results of the Meetings of the Commission

- (1) The Chair of the Commission informs the Rector of the Commission's opinions on matters submitted to the Commission for consideration without undue delay after the end of the Commission meeting.
- (2) The minutes are made available by the Chair of the Commission to all Commission members within 10 working days after the end of the Commission meeting on the team sites of the Commission in the University's electronic information system; other persons may consult the minutes only with the consent of the Chair of the Commission or if there are legal reasons for doing so.

Article 14

Complaint and its Discussion, Opinion on the Complaint

- (1) A member of the academic community of the University or other employee of the University ("the submitter") may submit a complaint⁴ pointing to a possible violation of the Code of Ethics of the University of Defence ("the Code of Ethics") by persons to whom the Code of Ethics applies in writing to the Chair of the Commission. The Chair of the Commission informs the Rector of the submission of the complaint without undue delay.
- (2) The complaint must contain the identification data of the submitter and a description of the act that is alleged to have violated the Code of Ethics, including the identification data of the person who is alleged to have committed the act. The Administrative Code⁵ applies mutatis mutandis to the assessment of the submission of the complaint. A model complaint is set out in Annex 1 to this Measure.
- (3) Anonymous submissions are not considered by the Commission.
- (4) The Commission considers the complaint and adopts an opinion on it no later than two months from the date of receipt of the complaint by the Commission unless a longer period has been set by the Rector for the adoption of the opinion.
- (5) The opinion of the Commission on the complaint includes, in particular
 - a) a statement as to whether a breach of the Code of Ethics has actually occurred and which ethical principle, with reference to the provisions of the Code of Ethics, has been violated,
 - b) an assessment of the seriousness of the conduct that violated the ethical principle,
 - c) a proposal for the scope of the publication of the information in the opinion ("the extract from the opinion").

⁴ Article 6 (2)(a) Measure of the Rector of the University of Defence No. 21/2021 – Organisational Regulations of the University of Defence.

⁵ Particularly Section 37 (1) to (3) of Act No. 500/2004 Sb., the Administrative Code, as amended.

- (6) The Chair of the Commission will forward the Commission's opinion on the complaint to the Rector and subsequently discuss the Commission's opinion with him/her. After discussing the Commission's opinion with the Rector, the Chair of the Commission forwards a paper copy of the Commission's opinion to the submitter and, where appropriate, to the persons concerned.
- (7) An anonymised extract from the opinion of the Commission will be published by Commission in the public section on the University's website no later than 30 days from forwarding the opinion to the submitter.

Article 15

Applications and Their Examination, Opinion on Applications

- (1) Application for assessing
 - a) a proposal of a research, development and innovation project at a university with human participants that is experimental in nature or includes an intervention programme of a fitness nature, including various forms of stress testing⁶,
 - b) a research proposal that is part of a thesis or habilitation project at a university with human participants that is experimental in nature or includes an intervention programme of a fitness nature, including various forms of stress testing⁷,
 - c) a proposal for a research, development and innovation project at the University not referred to in point a), if the opinion of the Commission is a condition for the approval of the project by the grant provider⁸, or
 - d) the result of scientific activity produced at the University, if the opinion of the Commission is a condition for publication of the result of scientific activity in a periodical publication⁹(hereinafter as "application") may be submitted by the applicant concerned in writing to the Chair of the Commission.
- (2) The relevant applicant is the principal investigator or another authorised member of the research, development and innovation project's research team or the author of the thesis, habilitation thesis or the result of scientific activity.
- (3) The application must contain all relevant information for the assessment of the subject matter of the application and, in the case of an application referred to in paragraph 1(a) or (b), it must be accompanied by the text of the informed consent to participate in the research and the text of the informed consent on the protection of personal data in the context of academic research. Example applications are set out in Annexes 2 and 3 to this Measure.
- (4) The Commission may invite the applicant to clarify his/her application, provide additional information or submit other necessary supporting documents without undue delay.

⁶ Article 6 (2)(b) Measure of the Rector of the University of Defence No. 21/2021 – Organisational Regulations of the University of Defence.

⁷ Article 6 (2)(b) Measure of the Rector of the University of Defence No. 21/2021 – Organisational Regulations of the University of Defence.

⁸ Article 6 (2)(d) Measure of the Rector of the University of Defence No. 21/2021 – Organisational Regulations of the University of Defence.

⁹ Article 6 (2)(d) Measure of the Rector of the University of Defence No. 21/2021 – Organisational Regulations of the University of Defence.

- (5) The Commission considers the application and adopts an opinion on it without undue delay but usually no later than 30 days from the date of receipt of the application by the Commission.
- (6) The opinion of the Commission on the application includes particularly
 - a) a description of the subject of the application,
 - b) an assessment of the ethical aspects of the subject matter of the application (including informed consent).
- (7) The opinion of the Commission on the application is forwarded by the Chair of the Commission to the Rector for his comments and signature, who returns it to the Chair of the Commission after completing his comments and signature. The opinion of the Commission on the application, bearing the Rector's opinion and signature, is forwarded by the Chair of the Commission to the applicant.
- (8) Where the project or research proposal referred to in paragraph 1(a) or (b) is, by its nature, subject to specific legislation (for example, in the field of specific health services¹⁰, clinical trials of medicinal products¹¹ or clinical trials of medical devices¹²), the applicant must comply with the obligations laid down in such legislation, and the opinion of the Commission is not required.

Article 16 Transitional Provisions

- (1) The members of the Commission appointed under the previous arrangement are deemed to be members of the Commission under this Measure; the period during which they were members under the previous arrangement is also included in the term of office of the members of the Commission.
- (2) A submission or an application made before the entry into force of this Measure shall be dealt with in accordance with the existing arrangements.

Article 17 Final Provisions

- (1) This Measure enters into force on the date of its signature by the Rector.
- (2) This Measure enters into force on 1 October 2023; on the same date, the Measure of the Rector of the University of Defence No. 18/2021, Ref. No. MoD 240278/2021-2994, Ethics Commission of the University of Defence, dated 25 October 2021, the Measure of the Rector of the University of Defence No. 5/2022 - First amendment of the Measure of the Rector No. 18/2021, Ref. No. MoD 93811/2022-2994, dated 16 March 2022, and the Measure of the Rector of the University of Defence No. 7/2022 - Second amendment of the Measure of the Rector No. 18/2021, Ref. No. MoD 194905/2022-2994, dated 30 May 2022, are repealed.

¹⁰ Particularly Act No. 373/2011 Sb., on Specific Health Services, as amended.

¹¹ Particularly Act No. 378/2007 Sb., on Medicinal Products and on Amendments to Certain Related Acts (the Medicinal Products Act), as amended.

¹² Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, and Act No. 375/2022 Sb., on Medical Devices and In Vitro Diagnostic Medical Devices.

Example Complaint regarding a Suspected Breach of the Code of Ethics

Chair of the Ethics Commission of the University of Defence

Kounicova 65
662 10 Brno

Pavel Novák
job classification,
workplace, part of UoD
Contact: e-mail, telephone

Submission of a Complaint to the Ethics Commission of the University of Defence

Dear Chair,

I am writing to you regarding a suspected violation of the Code of Ethics of the University of Defence.

Clarification of who, what and how one should have violated the Code of Ethics of the University of Defence, at what point, etc.

.....
.....
.....
.....
.....
.....
.....
.....

List of annexes to the complaint (only the documents that provide evidence for the allegations)

In view of the above, I believe that there has been a violation of the Code of Ethics of the University of Defence, and I request that my complaint be forwarded to the Ethics Commission of the University of Defence for consideration and subsequent notification of how my complaint was handled, or whether or not a violation of the provisions of the Code of Ethics of the University of Defence was found.

Yours faithfully

Date

submitter's signature.....

**Model Request for the Opinion of the Commission on a Research Project
or Research Proposal**

Request for the Opinion of the Ethics Commission of the University of Defence

on a proposal of a research, development, and innovation project at a university with human participants that is experimental in nature or includes an intervention programme of a fitness nature, including various forms of stress testing

on a research proposal that is part of a thesis or habilitation project at a university with human participants that is experimental in nature or includes an intervention program of a fitness nature, including various forms of stress testing.

Title:

Research is part of:

basic/applied research (for employees)

bachelor/master thesis x dissertation thesis x habilitation thesis

Principal Investigator/Processor (author):

Co-investigators:

Supervisor, thesis supervisor (in the case of a final thesis):

Statement of the supervisor, thesis supervisor (in the case of a final thesis):

Research description:

Research objective.

Reasons for engaging human participants.

Methods of recruiting research participants.

Ensuring safety for expert assessment:

- justification for the use of invasive methods, ways of minimising risks, safety certificates, the experience of the workplace and the responsible researcher with the methodology used, whether the device is state property and the university is entitled to manage it or it is used on a contractual basis,
- ensuring the protection of personal and sensitive data, personal rights and dignity of research participants, and the persons responsible for this protection (text of the research participation instructions).

Ethical aspects of research

Special justification for research in cases of involving minors, pregnant and nursing women, persons of reduced sanity, as well as prisoners.

Informed consent of the participants: YES x NO (if yes, provide text of consent)

In Brno on _____

Name and surname of the applicant: _____ Signature of the applicant: _____

Model Request for the Opinion of the Commission on a Research Project or Research Proposal

**Request for the Opinion of the Ethics Commission
of the University of Defence**

on a proposal for a research, development and innovation project at a university that does not have human participants or animals and that is not experimental in nature or does not include an intervention programme of a fitness nature, including various forms of stress testing if the opinion of the Commission is a condition for the approval of the project by the grant provider.

on a result of scientific activity created at a university, if the opinion of the Commission is a condition for publication of the scientific results in a periodical publication.

Title of the project proposal/result of the scientific activity:

Principal Investigator/Processor (author):

Co-investigators/co-authors and their contribution to the project/result of the scientific activity:

I request an assessment of the attached project proposal/result of scientific activity in terms of ensuring compliance with the ethical principles of scientific work in its implementation/assessing its ethical acceptability.

- a brief description of the research methods and the persons responsible for their correct use, a description of the activities of the individual members of the research team, and identification of the owner of the result of scientific activity.
- period of realisation
- place of realisation
- any attachments

In Brno on _____

Name and surname of the applicant: _____ Signature of the applicant: _____