# **Rector's Directive No. 40/2018**

# Code of Procedure for the Research Ethics Commission of Charles University

To implement: Article 4 of Rector's Directive No. 74/2017 – the Constitution of the Research Ethics Commission of Charles University

Date of effect: 18 November 2018

#### **Article 1 - Meetings of the Commission**

(1) Meetings of the Research Ethics Commission of Charles University ("the Commission") are convened and chaired by the chairperson, a substituting vice-chairperson, or another Commission member designated by them.

(2) Meetings of the Commission are closed unless the chairperson, an appointed vice-chairperson of the Commission, or a designated Commission member decides otherwise. This rule does not apply to Commission opinions.

(3) For the purposes of assessing a project proposal, the Commission has a quorum if a simple majority of Commission members participate in voting on a submitted project proposal.

(4) Meeting minutes are taken by a designated employee of the Rectorate. The minutes, as well as documents submitted by applicants, are filed in the Archive of Charles University in both printed and electronic forms.

#### **Article 2 - Submission of Proposals**

(1) Project proposals to be considered are submitted to the Commission via electronic mail.

(2) In the case of projects that pose little or no threat to participants, the applicant submits, as basis for the assessment, a brief description of the project, informed consent, and an affidavit in which he declares that the following conditions have been satisfied:

a) the research is not being carried out on vulnerable groups (e.g., minors, persons with restricted legal capacity, etc.);b) the research poses little or no threat to participants and is comparable to the risk posed by common office work or to the risk to which people are exposed during a regular day at work or school.

(3) In the case of projects that can pose medium or high risk to participants, the applicant must add the following information to that listed in the previous paragraph:

a) a description of procedures that decrease the risk posed to the participants, or rather minimisation of the negative impact on the participants, including procedures to everse the harmful effects of deception (if used in the research);
b) a detailed description of the situation analysis;

c) a justification of the necessity of the use of procedures that increase the risk posed to the participants;

d) if deception is used in the research, justification of the necessity thereof;

e) if the participants are from among a vulnerable population, justification of the necessity to carry out the research on those participants.

#### **Article 3 - Assessment of Project Proposals**

(1) The chairperson, or a substituting vice-chairperson, will send materials prepared by the applicant to other members of the Commission who then have 10 days to familiarize themselves with the materials and to raise objections to the project via electronic mail, or state that they have no objections.

(2) After all members of the Commission have expressed their opinion on the proposal, the members of the Commission have 10 days, which period starts to run no later than upon the expiration of the deadline under the previous paragraph, to familiarize themselves with comments made by all other members, and to vote on the proposal.

(3) As soon as the members of the Commission carry out the voting, the Commission issues a written opinion on the projects assessed which is signed by the chairperson or a substituting vice-chairperson, or another Commission member designated thereto by them.

## **Article 4 - Voting of the Commission**

(1) The Commission decides on the assessment of a project by a simple majority of all attending members. Commission members may vote making use of the means of electronic communication, or so-called remote voting. In such a case, a decision is adopted if a simple majority of all Commission members vote for the adoption of the decision. Each member of the Commission has one vote.

(2) A member of the Commission who is in conflict of interest with respect to a proposal under consideration cannot take part in the voting thereon.

(3) The Commission may either approve the proposed project or reject it along with a written reasoning.

(4) If the Commission suggests that a project be reworked, a new project proposal will be deemed as if it has not previously been submitted for assessment.

### Article 5

(1) This Code regulates the details of the consideration of the ethical risks of project proposals submitted at Charles University. The Commission considers project proposals relating to the entire University, or project proposals the consideration of which has been requested by one of the faculties, faculty commissions, or other units. This Code applies to other activities of the Commission listed in Article 3 of the Constitution of the Research Ethics Commission of Charles University with necessary modifications.

(2) This Directive becomes effective on 18 November 2018.

In Prague, 24 October 2018

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