

RULES OF PROCEDURE OF THE RESEARCH ETHICS COMMITTEE OF THE UNIVERSITY OF HRADEC KRÁLOVÉ

Article 1

Creation and Powers of the Research Ethics Committee of the University of Hradec Králové

- (1) The research Ethics Committee of the University of Hradec Králové (hereinafter the Committee) is established by the Rector as per Article 8 of the Rules for the Internal Governance of the University of Hradec Králové.
- (2) The Committee forms an integral part of the quality assurance system and compliance with ethic research standards at the University of Hradec Králové (hereinafter the UHK).
- (3) The Committee deals with ethic aspects of research performed at the UHK, including but not limited to human subjects (including the work with biological material of human origin) but also with other activities requiring assessment of ethics.
- (4) The research ethics is assessed in (but not limited to) the following cases:
 - Research concerns a human subject in any way (including the work with biological material of human origin);
 - The sponsor requires the ethics committee approval (e.g. H2020 research projects etc.);
 - The ethics committee approval is a precondition of publication in renowned professional journals.
- (5) Ethics of research performed by UHK students within their final theses is assessed in exceptional and duly justified cases only.
- (6) The Committee act on request of an applicant, typically a member of the UHK academic staff or the UHK student.
- (7) The Committee assess the research in accordance with the principles of freedom of research and take account of (but not limited to) the Czech Government Resolution No. 1005 of 17 August 2005 acknowledging the

Ethic Framework of Research, and of the recommendation of the Czech Ministry of Education, Youth, and Sports.

Article 2

Committee Membership

- (1) The Committee members become members by appointment. The Committee members are appointed by the Rector. Their term of office is the same as the UHK Rector's term of office. The Committee members are obliged to participate actively at the Committee activities.
- (2) The Committee has five permanent members out of which one chairs the Committee. The Committee chairperson is appointed by the Rector upon the proposal of the majority of all Committee members. The Committee composition allows complete ethics assessment of proposals submitted.
- (3) Such person may become the Committee member who:
 - a) Agrees with his/her Committee membership and with the publication of his/her Committee membership and other facts resulting from his/her activities and Committee membership;
 - b) Undertakes to observe confidentiality concerning the content of assessed application to prevent any misuse of information contained in such application;
 - c) Undertakes to declare any conflict of interests in advance if such conflict of interest could arise from his/her Committee membership; i.e. he/she abstains from presenting his/her views on applications in which he/she is interested personally.
- (4) A Committee member may be appointed repeatedly. The list of the Committee members is published on the UHK website.
- (5) The Committee membership is terminated by the member's resignation by his/her own written application, by the lapse of the member's term of office, or by the member's recall by the Rector.

Article 3

The UHK Activities

- (1) The Committee mission is to ensure protection of dignity, freedom, health, quality of life, and safety of all individual research participants.
- (2) Administrative and technical activities necessary for the Committee work are provided for by a secretary who is not a member of the Committee.

(3) The Committee ensure within their powers at the UHK that all research projects submitted to the Committee for assessment will be assessed through a competent, objective, and independent procedure. At assessment, the Committee pay special attention to protection of vulnerable or dependent individuals who participate in the research.

Article 4

Submission of Application

- (1) The application for assessment is submitted by the principal investigator of the research project, typically a member of the UHK academic staff or the UHK student.
- (2) The essentials of an application for assessment by the Committee are specified in Annex hereto (hereinafter the Application).
- (3) The Application is sent to the Committee secretary electronically. The secretary registers the Application and hands it over together with all documents to the Committee chairperson.

Article 5

Consideration of Application

- (1) A project that is to be assessed must be a project which has not been commenced yet and the term for its consideration before commencement if sufficient.
- (2) If a project has already been approved and commenced, its revision only may be considered.
- (3) If a project has been commenced before the UHK Ethics Committee establishment and must be assessed by the Ethics Committee, it may be considered exceptionally during its performance.
- (4) After the Committee chairperson receives the application and documents from the secretary, he/she informs other members about the application receipt and sends them the application and documents for preliminary assessment.
- (5) If the Committee agree so, they may ask a consultant(s) for his/her/their professional opinion. The consultants may only be chosen from a list drawn for this purpose and published on the UHK website.
- (6) The Committee members send their preliminary assessment to the Committee chairperson within the given period of time.

(7) The Committee draws a written opinion on the applications assessed. The applicant is informed electronically about the possibility to pick up the opinion in person from the Committee secretary, or to have it sent by post.

Article 6

Committee Meeting

- (1) The Committee meetings are convoked and chaired by the chairperson and/or, in the chairperson's absence, by a Committee member authorized by the chairperson.
- (2) Tor the purposes of an application assessment, the Committee has a quorum if the absolute majority of members are present.
- (3) The Committee meeting is held in private unless the chairperson decides otherwise. The meeting may be participated by consultants who provide to the Committee their profession opinions to the applications considered and other guests invited by the Committee, particularly the applicants.
- (4) The Committee meeting is participated by the secretary who draws minutes.
- (5) The meeting is not convoked if all Committee members approve the application as per Article 5 (6) and the consultants give approving opinion (see Article 5 (5)). In such case, Article 7 (3) hereof is applied and no meeting is held.

Article 7

Committee Voting

- (1) The Committee vote by acclamation at the meetings. Where justified, the chairperson may decide on secret ballot. The Committee voting is not public.
- (2) The member who declares conflict of interests related to the given application does not vote.
- (3) Applications having all approving Committee opinions (see Article 5 (6)) may be voted in writing without previous consideration at the Committee meeting. Applications with at least one disapproving opinion may be voted in writing only after previous consideration at the Committee meeting. The conditions of voting in writing are determined by the chairperson.
- (4) The absolute majority of voters is required for the proposal approval. In case of voting in writing, approval of the absolute majority of all Committee members who are not in a conflict of interests related to the given application is required.
- (5) The course and results of voting are recorded in a voting record.

Article 8

Conflict of Interests

- (1) The Committee member is in a conflict of interest if he/she:
 - a) Is the Applicant or member of the team of investigators of the project considered;
 - b) Has such personal or professional relation to the Applicant or other members of the team of investigators of the project considered that could influence his/her independence at the project consideration;
 - c) Is an Applicant or member of a team of investigators of a project submitted to the same tender as the project considered (in tenders organized by larger grant agencies, proposals submitted to the same panel or professional committee etc. are taken into account only).
- (2) The committee members are obliged to declare any potential conflict of interest at voting on the given Application. The Committee member who declares conflict of interests related to the given Application may not vote on such Application.
- (3) Consultants asked for a professional opinion as per Article 5 (5) hereof are also obliged to declare any potential conflict of interests.

Article 9

Final Provisions

These Rules of the Research Ethics Committee become valid and effective on the day of their signing and are issued in form of a Rector's Decree in accordance with the UHK Rules for the Internal Governance effective from 1 February 2018.

Annex - Application for Assessment by the UHK Research Ethics Committee

In Hradec Králové on 14 May 2018

Prof. Ing. Kamil Kuča, Ph.D., Rector

UHK Research Ethics Committee Rokitanského 62 500 03 Hradec Králové
Re: Application for Assessment by the Research Ethics Committee of the University of Hradec Králové
Subject of application/Project title/Article title ¹
Dear Madam/Sir,
I would like to ask you to assess the attached project/article (Annex 1) from the point of view of its ethic admissibility.
 Brief characteristics Period of implementation Site of implementation Attachments, if any
In Hradec Králové on
Applicant's name and surname, title and position
Address: E-mail:

 $^{^{\}rm 1}\,\mbox{Please}$ replace the parts written in $\it italics$ by your own text.