

Provisions of the Rector No 2/2020. (V. 26.) on setting up the CUB Ad Hoc Research Ethics Committee, and on issuing research ethics permissions

(transitional provisions)

In my role defined in Subsections a) and c) of Section 21(2) and pursuant to the mandate conferred on me by Section 21 (7) and (8) of the Rules of Operation and Organisation (ROO), in order to preserve the independence, impartiality, integrity, credibility of scientific research for those involved in research at the University as well as to ensure their ethical behaviour and uttermost professional fairness, I hereby issue the following provisions (hereinafter: Provisions) for a transitional period lasting until the adoption of the Research Ethics Policy:

1.§ Scope of the Provisions

- (1) The scope of the Provisions shall cover all research projects that are carried out from domestic or EU support, grant source (hereinafter research project) in which research is performed by a person who has an employment status with CUB (researcher, lecturer, grantee or doctoral student in a research group, student, guest researcher, guest lecturer in a project team) and either research ethics issues arise or compliance with such standards is to be considered irrespective of whether the researcher works individually, as part of a CUB group, or jointly with third parties.
- (2) The Provisions shall also apply to research projects for which an inquiry is made by an external researcher/a data access inquiry is made with respect to any person who has an employment or student status with CUB or with respect to their personal data.
- (3) The scope of the Provisions shall cover any persons acting as contributors, subjects in the research projects, persons dealing with research ethics issues as set out herein.
- (4) The Provisions shall define the scope of persons entitled to issue research ethics permissions as well as the procedure itself.

2.§ Ad hoc Research Ethics Committee

- (1) The Ad Hoc Research Ethics Committee (hereinafter "Committee") is an advisory body to the Rector as well as his decision-making body in individual authorisation matters. It shall report to the Rector.
- (2) Powers of the Committee:
 - a) may take a position in general matters of research ethics and has a right to make proposals to the Rector with regard to setting up standards.;
 - b) has decision making power in individual research ethics authorisation procedures;
 - c) has consultative rights and a right to make proposals to the Rector with regard to complaints submitted by parties prejudiced in the research project.
- d) The Chairperson of the Committee shall be the Vice-Rector for Research, its two members shall be entrusted by the Rector on a permanent or ad hoc basis. The Committee shall perform its duties within the scope defined in the terms of reference issued by the Rector (e.g. in the case of entrusting permanent members, in the event such a person is prevented from attending, or for a specific research field).
- e) The Committee may primarily have recourse to experts defined for the relevant individual authorisation

procedure (such as experts from other research fields, data protection experts). The legal background documents and support shall be provided to the Committee by the Economic and Labour Law Services. The experts shall not have voting rights at the meetings of the Committee.

3.§ The Committee's Tasks and Powers

- (1) The Committee's task shall be to draw up the draft Research Ethics Policy in co-operation with the members of the invited working group.
- (2) It shall make proposals to the Rector with regard to setting up standards in research ethics matters.
- (3) It shall examine individual issues of research ethics, including
 - a) it shall conduct individual research ethics authorisation procedures
 aa) in case of research projects carried out at CUB financed from a source specified in Section 1(1) above,
 ab) in case of research applications with the participation of CUB jointly with other institutions, legal entities performing research,
 - ac) in case of research projects initiated pursuant to Section 1(2) above;
 - b) it shall have the right to issue resolutions on the basis of an inquiry from any university citizen, in any research ethics matter for which the observation of research ethics standards is to be considered;
 - c) it shall have the right to comment on and make proposals to the Rector with regard to complaints.
- (4) Within its powers, the Committee shall be entitled to decide to issue or refuse research authorisations with respect to the submitted applications, or in cases set out in Section 1 (2) above, to recognize the research ethics permission of one of the institutions involved in the research project if
 - a) the leader of the research project is an employee of CUB and holder of a doctoral (PhD, CSc, DSc) degree or its Professor Emeritus, Emerita;
 - b) in cases set out in Section 1(2) above, the researcher's, the research project leader's scholarly performance at another institution is verified.
- (5) Research projects in which the researcher, the leader of the research project do not meet the criteria defined in a) or b) above shall not be accepted.
- (6) Within its powers, the Committee shall be entitled to inspect authorized university research projects either at random or upon being notified. In this context, the Committee is entitled to consult the research documentation, to raise both written and oral questions. The findings of the inspection shall be drawn up in a report addressed to the Rector. The leader of the research project, professional leader or any other person involved in the audited project shall be obliged to co-operate with the Committee or any person invited by the Committee to carry out the inspection. It shall initiate an ethical procedure as a result of the inspection in case it identifies non-compliant behaviour with the criteria laid down in the research ethics authorization.
- (7) The Committee shall seek to raise the ethical awareness of the university's researchers through providing clear and timely information and offering constructive discussions, in particular during individual authorization procedures and the consultations leading up to the drafting of the CUB Research Ethics Policy.

4.§ The Committee's Rules of Procedure

- (1) The Committee shall hold its meetings as necessary either on its own initiative or as required by the urgency of the submitted matters, but not later than within 8 working days of the receipt of the submission by the secretariat during term-time and within 30 working days thereof in the summer break. The meeting shall be convened by the Chairperson via e-mail 3 days prior to the meeting, specifying the time, the place and the agenda of the meeting, and if possible attaching the proposals.
- (2) The Committee may also deliberate electronically if necessary, or a member, expert may join the face-to-face meeting electronically via the session created by the Chairperson on the online collaboration platform (e.g.

- MS-Teams). In such cases the members of the Committee shall decide on the proposal tabled by the Chairperson via e-mail.
- (3) The Committee's procedure may be initiated by the Rector, the Chairperson or a member of the Committee, or a natural person falling within the substantive scope of the present Provisions via e-mail or on paper in the format specified in Subsection (4) below by defining the request in accurate terms, its grounds as well as by describing the circumstances.
- (4) The Committee shall be entitled to define and publish on the webpage of the Vice-Rector for Research the formal and substantive requirements that submissions sent to the secretariat of the Vice-Rector for Research should meet (e.g. confidential treatment can be ensured by "password-protected compression"). In case the submission is not identifiable, it shall not be included in the agenda by the Committee.
- (5) Within any of its mandated powers, the Committee may have recourse to experts. If personal data are processed within the framework of the research project which is the subject of the research ethics authorization or if this cannot be clearly established, a data protection officer shall be involved.
- (6) The sessions of the Committee shall not be public, however a public session may be held on the Chairperson's or a member's initiative and upon the decision of the Committee. The person serving as secretary to the Committee may take part in the closed session as well as the invited expert during the discussion of the relevant agenda item.
- (7) The secretariat of the Vice-Rector for Research shall serve as secretary to the Committee.

5.§ Decision-making

- (1) A quorum shall exist if all the three Committee members are present (in person or electronically) during the discussion of the given agenda item.
- (2) During the discussion of the given agenda item, the Committee shall take decisions in an open vote, with the unanimity of those present with voting rights.
- (3) If necessary, the Committee may request additional information or modifications (hereinafter request) from the applicant no more than twice by setting a deadline of three working days and if necessary, it may even hear the applicant. It shall summon the applicant via e-mail and mobile phone. In case the applicant fails to appear, the Committee shall take its decision on the basis of available documents.
- (4) The Committee shall decide on authorisation matters within 60 days of the submission of the application. Such deadline shall be extended by the time limit set for responding to the request and due to the hearing.
- (5) The decisions (resolutions, decisions in authorization matters) of the Committee shall be issued by its Chairperson. The secretariat of the Committee's Chairperson shall publish the resolutions and decisions taken in authorization matters on the research page of the university's website.
- (6) Any decision taken in research ethics authorization matters shall be binding for every research project leader, researcher and persons involved in the research project, no derogations shall be made. Should the applicant fail to comply with the request or complies with it only partially, the Committee may reject the application. There shall be no right of appeal against the decision.
- (7) Any party prejudiced during the research project may seize the Committee as a complainant. The Committee shall deliver its opinion on matters submitted by the complainant and shall forward it to the Rector together with its proposal. The Rector in turn shall decide on defining and launching any additional procedure.
- (8) In the event of an infringement pursuant to Section 6(11) below, the Committee shall, within 8 working days of becoming aware thereof, make a proposal to the Rector to initiate the ethics review.
- (9) The Committee shall record and archive each decision resolutions and decisions made in individual cases.

(10) Administrative support to the secretariat of the Committee shall be ensured by the Economic and Labour Law Services.

6.§ The Process of Research Ethics Reviewing

- (1) The launch of any research project involving direct or indirect collection of data (data recording) from human participants and their analysis shall be subject to a research ethics self-review procedure, to holding a permission and to meeting the requirements formulated therein.
 - (2) The following research forms shall be subject to obtaining a permission:
 - a) direct data collection from participants (in instances of intervening and non-intervening participation), and
 - b) indirect data provision with regard to a person connected to the participant (e.g. parent provides data on child, superior on subordinate).
- (3) The Committee shall be entitled to issue research ethics permissions in line with the ethical principles of social science research.
- (4) Prior to launching any research project, a self-review along the principles of social science research shall be undertaken for any research project involving human participants. By completing the Review Questionnaire attached hereto as Annex 1 and by conducting an ethical risk analysis the researcher, the leader of the research project shall assess whether the research is acceptable from the viewpoint of research ethics, whether he/she has made every effort during the planning of the research to ensure that the research participants are not exposed to any harm or are only exposed to minimal harm within the given methodological framework.
- (5) The ethical risk analysis shall assess the risks/potential damages as well as the results/benefits arising from the research, whether there is a likelihood of causing damage/harm at the level of the individual/group/society during the research, and what the potential benefit of the research can be.
- (6) Measures to be taken to minimize risks (e.g. omitting unnecessary risk factors, replacing them by factors involving less risk, requirement of providing follow-up information) shall be taken.
- (7) The necessity of applying for a research ethics permission can be established as part of the research plan by the researcher, the leader of the research project by filling in the Review Questionnaire and can be initiated by sending it to the Committee via e-mail. The Review Questionnaire and the ethical risk analysis shall be included in the research documentation.
- (8) Subject to the category established on the basis of the Review Questionnaire, the procedure shall be as follows:
 - a) permission is not required for the research if none of the questions in Part 2 of the Review Questionnaire
 has been answered in the affirmative;
 - b) in the case of **low concern**, that is minimal ethical risk, it is sufficient to consider the criteria set out for the given ethical aspect, to respect the relevant protocol if some of the questions in Part 2 have been answered in the affirmative.
 - ba) The Review Questionnaire shall be submitted, however, if the ethical issues arising during the research are appropriately addressed, there are no further ethical issues/risks involved, and therefore the permission can be issued without requesting additional information.
 - bb) If the ethical issues are not appropriately addressed in the Review Questionnaire, the Committee shall issue a call as to how the information provided in the Review Questionnaire should be modified to obtain the permission.

- c) Higher concern under (7), that is when the risks involved exceed the minimum, besides filling in the Review Questionnaire it is necessary to apply for a research ethics permission with respect to the entire research plan. The Committee shall evaluate the research plan as a whole, it shall assess whether the intended methods are suitable from a research ethics viewpoint to achieve the research objectives. Issuing the permission shall be subject to modifying the research plan and to making the relevant changes in the information provided in the Review Questionnaire on the basis of the Committee's evaluation.
- (9) Risks exceeding the minimum level (higher concern) might occur in the following cases:
 - a) **vulnerable populations, groups** (that need other's care and protection, have a handicap or do not possess the knowledge that would enable them to wholly understand the implications of the research concerning them, that is for which providing an adequate background for an informed consent requires particular attention. The participating person **may be considered vulnerable** if he/she is a minor, suffers from a mental or physical disability, has a cognitive impairment, is an expectant mother, is aged, is a student, is a member of the armed forces, suffers discrimination, is serving his/her sentence/has been convicted, is a refugee, is an illegal immigrant, is a sex worker /offers sex services for money, belongs to the political opposition/minority; is traumatised and may be exposed to repeated traumatization (e.g. comes from an area involved in armed conflict; is the victim of a crime or aggression), is dependent on the researcher, the members of the research group (e.g. students attending the researcher's course/class, subordinates of the person conducting the research at the institution), etc.
 - b) **sensitive research topics** (e.g. concerning sexual/illegal/political behaviour; aggression/abuse/exploitation, mental health, personal/family life; gender issues/ ethnical status; persons in prominent positions),
 - c) in the event of risk of psychological stress, access by the researcher shall be subject to the permission of the supervising person or organization (e.g. communities, social and educational institutions, research within an organization);
 - d) the methodology includes **deception/interventional procedures**, **hidden research**, data collection;
 - e) **recording of sensitive personal data** (the issue of individual identifiability may arise during the data collection: research projects using data collected on the internet, on social media and using, creating images that are suitable for the purposes of identification);
 - f) in the case of *dangerous research locations* where research exposes the researcher to risk;
 - g) the use of the research findings *may provide an opportunity for abuse*.
 - (10) The researcher, leader of the research project, member of the research group shall be bound to act in accordance with the Committee's evaluation and request, to withdraw from the given research activity or in cases subject to a permission, to perform the research in the way specified in the permission.
 - (11) Any breach of the present Provisions or of the application for permission procedure during the research (e.g. failure to carry out the self-review, failure to include the Review Questionnaire in the research documentation), or any action, conduct that is not in line with the permission shall be considered as an ethical abuse, provided that more serious breaches have not occurred.

7.§ Miscellaneous

(1) The present provisions shall enter into force on the day of their publication and shall apply to any research project launched after their effective date.

Annex 1: Review Questionnaire

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