

Rules of Procedures of the Ethics Committee for Human Subjects Research of the J. Heyrovský Institute of Physical Chemistry of the CAS

Clause 1 - Introduction

The roles and competencies of the Ethics Committee for Human Subjects Research of the J. Heyrovský Institute of Physical Chemistry of the Czech Academy of Sciences (HIPC) (hereafter referred to as the “Ethics Committee”) are defined in the Statute of the Ethics Committee for Human Subjects Research approved on 5.03.2018. The Ethics Committee deals with the ethical aspects of research involving human subjects carried out at the HIPC or by persons cooperating with the HIPC. The Ethics Committee's purpose is to protect the health, rights and dignity of all participants recruited for the research.

Clause 2 – Ethics Committee for Human Subjects Research

1. The meetings of the Ethics Committee are convened and chaired by its Chair, Vicechair or a Member of the Ethics Committee authorised by the Chair.
2. The Ethics Committee is quorate for examining an Application for Ethical Approval for research involving human subjects if an absolute majority of the Ethics Committee members can vote on the submitted study (Clause 5.2).
3. The Ethics Committee meetings are non-public unless the Chair decides otherwise.
4. The minutes of the Ethics Committee meeting shall be taken by an authorised member of the Committee. These minutes and the documents submitted by the applicants are then archived at the HIPC in printed form.

Clause 3 – Ways to Submit the Application for Ethical Approval

1. Applications for Ethical Approval are submitted to the Ethics Committee for assessment via an electronic interface accessible on the HIPC website and by following the listed requirements. All documents for the Ethics Committee have a standard format and must be substantive and concise.
2. The applicant submits the “Application for Ethical Approval” together with a brief Annotation of the study, including the study protocol(s) and the text of the Informed consent form.
3. For studies that may pose a higher risk to the recruited participants (higher compared to the risk to which people are exposed during a normal day at work or school), the applicant must add the following information compared to the previous point:
 - a. a description of procedures that lead to the reduction of risks for recruited participants or minimization of negative impacts on participants, including procedures to eliminate the consequences of deception (if applicable);
 - b. justification for the necessity of the procedures that increase the risk for participants;

- c. if deception is used in research, justification of its necessity;
- d. if the participants are from vulnerable groups, the justification for the necessity of conducting research on these participants.

Clause 4 – Assessment of proposed studies

1. The Ethics Committee keeps a record of all submitted applications according to the date of receipt and informs the applicant in case of their incompleteness.
2. The Chair, the Vicechair, or a Member of the Ethics Committee authorized by the Chair sends the documents submitted by the applicant to the other members of the Ethics Committee. Committee members have one calendar week to familiarize with these documents and express their objections or declare that they have no objections via a closed electronic discussion portal.
3. The Ethics Committee has the right to request additional materials necessary for the assessment of the proposal from the applicant.
4. Once all committee members have expressed their opinion on the proposal, but no later than the deadline for comments (see paragraph 4 of Clause 2), committee members have one calendar week to review the comments of other members and vote. If a committee member does not vote within the specified period, it is assumed that they abstained from voting.
5. After voting, without any unnecessary delay, the Ethics Committee issues a written decision on the proposals under consideration, signed by the Chair, the Vicechair, or a member of the Ethics Committee authorised by the Chair.
6. The method of voting (non-public, public, or *per rollam*) is selected by the Chair, the Vicechair or a Member of the Ethics Committee authorised by the Chair.

Clause 5 – Vote by the Ethics Committee

1. A member of the Ethics Committee who is in a conflict of interest with the submitted research cannot participate in the voting, especially if she or he is the applicant or co-applicant of the study.
2. The proposal is accepted if a majority of participants in the vote are in favour of the submitted case.
3. The Ethics Committee can either approve or reject the proposed project. In the case of rejection, the Committee shall justify its decision and provide recommendations for its improvement.

Clause 6 – Final Provisions

1. The written decision must include:

- a. the exact title of the assessed study;
 - b. the name of the applicant;
 1. identification number, or date of the evaluated protocol;
 - c. a list of evaluated documents,
 - d. statement of the decision of the Ethics Committee;
 - e. in the case of rejection, clearly express the requirements of the Ethics Committee with justification.
2. The minutes of the meeting of the Ethics Committee must name the members of the Ethics Committee who voted for or against the final resolutions of the Ethics Committee or abstained from voting. In the case of a secret vote, the number of positive, and negative votes and the number of members who abstained must be stated.
 3. Documentation related to the administrative steps of the Ethics Committee is kept for 5 years.

These Rules of Procedures were approved at the Ethics Committee meeting on 11.12.2020.

Prague, 19.12.2020



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Chair of the Ethics Committee