UNIVERSITÉ DE GENÈVE

Regulations of the University Commission for Ethical Research (CUREG2.0)

Regulation currently under review (this version remains in force until the new version takes effect).

Preamble

In 2017, the University of Geneva created a University Commission for Ethical Research in Geneva, known as CUREG. In 2020, following the recommendations issued by the Committee on Ethics and Professional Conduct of the University of Geneva and the Geneva University of Applied Sciences and Arts of Western Switzerland (HES-SO), CUREG became the only research ethics committee for researchers from all University faculties, centers and institutes and was renamed CUREG2.0.

CUREG2.0 exercises its powers independently, taking into account the principles of the *Code of Ethics and Professional Conduct* of the Geneva institutions of Higher Education, as well as other principles and rules applicable to ethical matters.

Article 1: Purpose

The present regulations establish the missions and the mode of operation of the University Commission for Ethical Research in Geneva (hereafter: CUREG2.0).

Article 2: Missions

1. CUREG2.0 carries out the ethical evaluation of research projects (hereinafter: the "project(s)") conducted at the University of Geneva by a staff member or a student under the responsibility of an academic supervisor of the University (the "researchers") and that:

   - involve human participants but are outside the scope of Geneva Canton's research ethics committee (CCER), which is Geneva's cantonal authority responsible for implementing the Swiss Federal Human Research Act (RS 810.30);

   - take place in open spaces – typically outside a laboratory – and could have an adverse impact on the environment; and/or

   - are deemed to be multiple-use projects, i.e., their results could have military, security, political or intelligence-related implications.

2. Where necessary, CUREG2.0 also assesses inter-institutional research projects involving a researcher from the University of Geneva.

3. CUREG2.0 identifies and validates the ethical principles and rules applicable to the research mentioned in numbers 1 and 2 above.[1]

4. It promotes the training of researchers in the field of research ethics.

5. It advises researchers on ethical issues related to research.

Article 3: Membership

1. CUREG2.0 members include:

a) the Vice-rector for Research;

b) an ethics expert appointed by the Rectorate;

c) at least 23 professors of the University of Geneva, including:

a. at least six representatives from the *Faculty of Psychology and Educational Sciences* (FPSE), with at least one representative from each of the Faculty's units;
b. at least four representatives from the *Geneva School of Social Sciences*;
c. at least one representative from the *Faculty of Translation and Interpreting*;
d. at least one representative from the *Faculty of Humanities*;
e. at least one representative from the *Faculty of Theology*;
f. at least two representatives from the *Faculty of Law*;
g. at least two representatives from the *Geneva School of Economics and Management*;
h. at least four representatives from the *Faculty of Science*;
i. at least two representatives from the *Faculty of Medicine*, including an expert in psychiatry;

d) an expert in military, security, political or intelligence matters;

e) at least three members of the teaching and research staff of the University of Geneva, holding a doctorate proposed by the Faculties or the Interfaculty centers and Institutes;

f) two staff members from the Research Services, including the person responsible for the application of data protection regulations in research projects;

g) a staff member from the Scientific Information Division (DIS) involved in activities related to data management;

h) the head of the security of information systems within the University of Geneva;

i) a staff member of the Communications Department, in charge of examining the potential repercussions in terms of image for the institution.

2. Each Dean's Office proposes its faculty representatives mentioned in number 1 letter c, who are then appointed by the Vice-Rector for Research.

[1] The reference documents containing the ethical principles and rules on which CUREG2.0 bases its work are listed on the CUREG2.0 website (https://cureg.unige.ch).

3. The experts listed in paragraph 1(d) and the staff members listed in paragraphs 1(e), (f), (g) and (i) are appointed by the Vice-Rector for Research.

4. All members of CUREG2.0 are committed to contributing their experience and knowledge to the management of ethical aspects of research at the University and/or to helping validate the procedures put in place by CUREG2.0.

5. CUREG2.0 members commit to regularly reviewing all or part of the projects submitted to CUREG2.0 by contributing to the assessments assigned to them.

6. CUREG2.0 members are expected to carry out their mandate in a diligent, caring and confidential manner and to be available to participate in CUREG2.0 sessions.

7. On the proposal of a recommendation by a member, the Committee Chair of CUREG2.0 may at any time call upon experts from within or outside the University of Geneva in an advisory capacity.

8. With the exception of the Vice-Rector for Research, the staff member in charge of data protection from Research Services and the head of IT security, together with their substitutes, CUREG2.0 members are appointed for a four-year term that can be renewed twice. If a member resigns, can no longer fulfill his/her role or has his/her membership revoked, a new member or a substitute will be appointed by the relevant entity. The newly appointed person completes the current term.

9. The plenary sessions are convened by the Committee Chair and are recorded in the minutes.

10. During plenary meetings, decisions of CUREG2.0 can only be taken if at least ten of its members are present, including six professors, with at least three FPSE representatives and one representative from the same faculty, center or institute as the researcher concerned, provided the center or institute has a CUREG2.0 representative. Decisions of CUREG2.0 are taken by a simple majority of the members present. In the event of a tie, the Chair has the casting vote.

Article 4: Committee Chair

1. CUREG2.0 is chaired by the Vice-Rector for Research. The Chair will appoint at least three Vice Chairs from among the professors of the University of Geneva sitting on the commission, including one FPSE representative. The Chair, the ethics expert and the Vice Chairs make up the CUREG2.0 Committee Chair (the " Committee Chair").

2. The Committee Chair has the following responsibilities:

   - It ensures that the composition of CUREG2.0 is in keeping with Article 3 above and that the interfaculty centers and institutes are represented.

   - It appoints one or several assistants who are trained in ethics-related matters, report to the Committee Chair and are responsible for the day-to-day management of CUREG2.0 (hereinafter referred to as the "CUREG2.0 management unit").

   - It validates the selection of panel members and external experts proposed by the CUREG2.0 assistant to review a project.

   - It oversees the activities of the administrative staff attached to the CUREG2.0.

- After analyzing the assessment report, it decides whether the evaluation of a research project should be carried out to the standard or simplified procedure, or whether it should be discussed in a plenary session.

- It calls and chairs plenary meetings.

- It can be consulted on any question related to scientific integrity within the University, particularly within the framework of procedures carried out in this field.

Article 5: Operating principles

a) The decisions of CUREG2.0 are based on the elements transmitted by the researchers, who is responsible for the completeness and veracity of the information transmitted.

b) The information provided by the researcher is examined to identify any risks. This entails assessing the likelihood and severity of any potential damage, as well as the mechanism proposed by the researcher to mitigate those risks.

This information includes, but is not limited to:

a. the sources of funding for the research ;

b. the level of responsibility of the applicant;

c. the description of the project, objectives, materials used, location, duration of the project, etc;

d. the recruitment pool and procedure, the target population, the target environment;

e. the possible compensations, advantages and benefits for the participants or for the environment;

f. the measures taken to ensure confidentiality and data protection, and details of how results will be published;

g. the measures taken to ensure that participants give their free and informed consent;

h. the potential military, security, political or intelligence interest of the results;

c) CUREG2.0 makes no judgment on the value and/or scientific relevance of the projects submitted, unless the evaluation committee identifies that the risk-benefit balance analysis is too unfavorable.

d) The Faculties and Interfaculty Centers and Institutes contribute to the administrative and/or scientific management of CUREG2.0 in proportion to the number of applications submitted by the researchers affiliated with them.

Article 6: Assessment procedure

1. Self-assessment by the researcher

The researcher performs a self-evaluation of his/her project using a questionnaire that he/she fills out online on the CUREG2.0 website, which allows him/her to identify the ethical risks of his/her project.

For students, the academic supervisor of the project submits the evaluation questionnaire.

The CUREG2.0 assistant examines the questionnaire and issues a notice which he/she sends to a member of the Committee Chair for a position.

If no ethical risks are identified by the Committee Chair, CUREG2.0 will issue *a statement of ethical compliance* to the researcher.

If the member of the Committee Chair identifies an ethical risk, CUREG2.0 will inform the researcher that he/she must submit a detailed description of the project for full review by CUREG2.0.

2. Full project review

The researcher submits his/her completed application for evaluation online on the CUREG2.0 website.

Upon receipt of the application, the Chair appoints a review panel composed of at least three experts, usually members of CUREG2.0, including two representatives of faculties, inter-faculty centers and institutes whose research or teaching themes are similar to those of the project, and a member in charge of evaluating the management of scientific data and, if applicable, the risks related to the protection of personal data.

Where necessary, an expert from outside CUREG2.0 may be appointed.

Each member of the review panel sends his/her comments in writing to the CUREG2.0 assistant. The latter will make an initial summary and issue an opinion and, if necessary, recommendations, in the form of an assessment report, which he or she will forward to the Committee Chair.

On the basis of this report, the Committee Chair decides whether the standard procedure (point 3 of this article) or the simplified procedure (point 4 of this article) is to be applied for the examination of the project.

The standard procedure is applied in particular in the following cases:

- serious and/or high probability risks;
- divergence in the opinions and/or recommendations of the assessors;
- at the explicit request of a member of the Committee Chair, one of the panel members or the CUREG2.0 assistant.

3. The standard procedure

The Committee Chair shall convene a plenary session of CUREG2.0 to discuss and come to a decision on the project and the assessment report, and shall appoint one of the panel members as the rapporteur.

Based on the project and the assessment report, CUREG2.0 will decide:

- to grant authorization for the project to go ahead with no conditions;

- to grant authorization to carry out the project subject to compliance with the recommendations of CUREG2.0;

- to refuse authorization to carry out the project

The decision is sent to the researcher.

3.1 Issuance of authorization to carry out the project with conditions

When CUREG2.0 authorizes the project to proceed, subject to the implementation of the recommendations, the researcher submits a revised version of the project to CUREG2.0, taking into account the recommendations made.

The CUREG2.0 assistant checks the revised version and sends it to the rapporteur and the Committee Chair.

If they consider the revised version to be sufficiently responsive to the recommendations, CUREG2.0 will grant approval for the project to proceed. If the latter consider that the revised version does not sufficiently take into account the recommendations made, authorization may be refused, or a new set of modifications may be requested.

If additional major revisions are needed, the revised version may also be submitted to the plenary session for discussion and decision.

If the project is rejected after a second review, the decision, made in plenary, is deemed final.

3.2 Refusal of authorization to carry out the project

When CUREG2.0 considers refusing authorization to carry out the project, the researcher has the right to be heard by the Committee Chair.

After hearing the researcher, the Committee Chair confirms the decision of CUREG2.0 or decides to reconsider it by making recommendations. In the event of a confirmed refusal, the researcher may resubmit a substantially revised project for a new procedure.

4. The simplified procedure

Based on the project and the assessment report, the Committee Chair will decide to:

- issue the authorization to carry out the project without conditions;

- issue the authorization to carry out the project on the condition that the recommendations are implemented in a revised version of the project.

The decision is sent to the researcher.

When the Committee Chair grants authorization to carry out the project, subject to implementation of the recommendations, the researcher submits a revised version of the project to CUREG2.0, taking into account of the recommendations made.

The CUREG2.0 assistant will then conduct a preliminary verification of the revised version and submit it to the Committee Chair.

If the Committee Chair considers that the revised version adequately addresses the recommendations, it will authorize the project to proceed.

If the Committee Chair considers that the revised version does not sufficiently take account of the recommendations, it may:

- request a new revision of the project based on the recommendations;

- request a review by the CUREG2.0 plenary session to the standard procedure, if the revisions are deemed insufficient after the second review.

Article 7: Project monitoring

The project may only begin once authorization has been obtained.

When a certificate of ethical compliance or authorization to carry out the project is issued by CUREG2.0, the researcher must inform CUREG2.0 of any subsequent changes to the project. If the modifications do not raise ethical issues, the Committee Chair will decide. If the modifications raise ethical and/or legal issues, the application is submitted to the simplified procedure.

If, during the course of the project, it becomes apparent that the health and/or safety of the participants is compromised, or that the environmental impact is worse than initially anticipated, the researcher must inform the Committee Chair as soon as he/she is aware of this. In such a case, the CUREG2.0 may revoke or suspend the certificate of ethical compliance or the authorization to carry out the project, or may impose new conditions on the project.

The Ethics and Professional Conduct Committee of the University is the body of reference for dysfunctions in the conduct of projects evaluated by CUREG2.0. and, if deemed necessary, it may ask the Rectorate to investigate.

Article 8: Declaring conflicts of interest, and withdrawals

1. The members of CUREG2.0 as well as the mandated experts have the obligation to declare to the Committee Chair any conflict of interest with respect to the projects that are discussed or with respect to the researchers that they have to evaluate.

2. The CUREG2.0 members have the obligation to announce and to recuse themselves when :

a) they are directly or indirectly involved in the project, or have a personal interest in the project

b) they have a hierarchical link with the researchers involved in the project, whether it is a link of authority or subordination;

c) they have a personal relationship with the researchers involved in the project (family, living together, ...);

d) they are involved in the project in some other way.

3. In all other cases, the Committee Chair will look at the circumstances as a whole and decide whether the member has to withdraw or not.

4. Members who have to withdraw cannot take part in any discussions or decisions concerning that particular project.

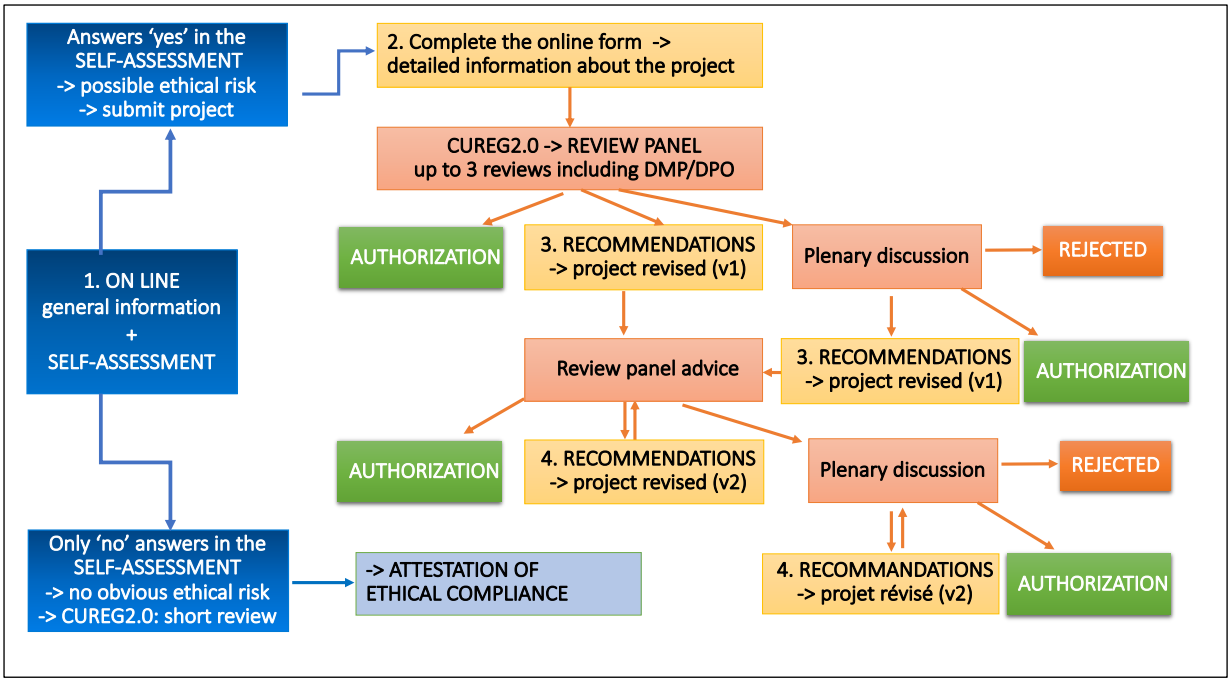
Article 9 Non-disclosure requirement

In addition to any other confidentiality to which they may be bound by virtue of their profession or position, the members of CUREG2.0, the experts appointed by it, the CUREG2.0 assistant and any other person participating in the assessment process are required to maintain confidentiality regarding the research projects submitted to them. This obligation continues after the end of their mandate or function.

Article 10 Entry into force

These regulations replace the Regulations of the University Commission for Ethical Research in Geneva dated 1 August 2017. They were adopted by the Rectorate at its meeting on 14 December 2020 and come into force on January 1, 2021.

Appendix 1: Diagram showing the assessment procedure for projects submitted to CUREG2.0



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