

Research Ethics Committee, University of Toulouse

Implementation of rules on ethics and professional conduct

INTERNAL REGULATIONS

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1. PREAMBLE

The aim of this document is to define rules for the establishment and functioning of a Research Ethics Committee (REC) for the purpose of providing opinions on research protocols at the request of researchers. Referral to this Committee shall neither be systematic nor obligatory. The REC shall obtain IRB accreditation. The REC operates according to these internal regulations and is based on a charter.

2. TASKS

The REC examines and provides an opinion on ethical aspects of research projects directly or indirectly involving humans that are referred to it by a researcher or teacher-researcher working at an institution pertaining to the Université Fédérale Toulouse-Midi-Pyrénées (Federal University of Toulouse-Midi-Pyrénées, FUTMP) or partner institution (for example, the internal research units of the Centre National de la Recherche Scientifique, CNRS).

The committee provides an advisory opinion on authorisation to implement the submitted project in view of the risk/benefit ratio raised by such implementation. The main aim of the committee is to encourage “good practice” by researchers with regard to research ethics.

Research on humans involves a large amount of personal data processing. The committee undertakes to inform applicants of the need to ensure that each person's identity, private life and individual and civil liberties are respected.

3. SCOPE

Any survey or research project related to the tasks of the REC, as defined in clause 2 of these regulations, may be referred to it.

However, in the case of a request for an opinion requiring IRB certification, certain projects are excluded from the committee's scope of intervention. They concern research activities in which the involvement of human subjects concerns one or more of the following categories:

1/ Studies of a biomedical nature involving a complex investigation mechanism: (a) invasive studies requiring the skin barrier to be crossed (collection of a blood sample or injection of a product), and (b) studies involving onerous means that may be difficult for participants to bear, or those requiring a medical presence (magnetic resonance imaging, centrifuges, electrical stimulation, etc.).

Authorisation for such studies comes under the responsibility of the Committee for the Protection of Individuals, which must issue a favourable opinion (Articles L1121-5, L1123-7 and R 1123-21 of the French Public Health Code).

2/ Studies that only require the agreement of an institution: (a) studies conducted at recognised teaching institutions, solely involving ordinary educational practices such as, for example, studies concerning educational programmes (including special education), or comparative studies on the effectiveness of various educational techniques (e.g. classroom management methods), and (b) studies using educational testing (cognitive tests, diagnostic tests, aptitude tests, performance tests), investigative techniques, monitoring procedures, except in cases where the information gathered is coded in such a way that the participant can be directly or indirectly identified, disclosure of the participant's responses could prejudice the latter's reputation or financial situation or incur their civil liability, or the participant is a candidate for employment in the public sector or is in public office.

3/ Documentary studies, for example, studies concerning existing documents, provided that they are freely available for consultation and that the participants in such studies are made anonymous.

4/ Satisfaction surveys or assessments: (a) studies on assessments by consumers of food quality and taste if the latter do not contain any additives or contain additional ingredients up to the levels permitted by health regulations, and (b) studies aiming to assess public service programmes subject to the approval of the relevant Government agencies or departments.

An opinion issued by the REC concerning a research project does not in any way affect researcher responsibility and liability. The opinion issued essentially indicates that the researcher requested the opinion of other professionals and that the project as described was considered to meet the research ethics principles observed by the REC.

The REC shall not examine the scientific interest of the research protocol submitted to it, nor the method used except in the following two cases: (a) if the protocol raises an ethical issue that gives reason to believe that the participant incurs a risk other than those habitually incurred in everyday life, or (b) if the protocol was submitted in order to obtain an IRB number.

4. ESTABLISHMENT

4.1 Composition of the REC

The REC is composed of at least 5 members, divided into 2 panels, including:

- Panel 1: members appointed by the Academic Board because they belong to disciplines concerned by the research that falls under the scope of the REC
- Panel 2: members appointed by the Academic Board because they belong to one of the following categories: (a) scientific ethics experts, such as, for example, a member or former member of a Committee for the Protection of Individuals, (b) practising psychologist, (c) legal expert, (d) philosopher, (e) CNIL (French data protection authority) correspondent or data protection officer, and (f) at least one person from a body representing the voluntary participants in research protocols.

The list of members is updated annually by FUTMP's Academic Board and published on the REC's website.

4.2 Appointment of members

A commission from the FUTMP Academic Board prepares a call for expression of interest, which it publicises as widely as possible among its member and partner institutions, their governing bodies and research centres.

It collects applications and appoints the members of the REC after consulting the REC bureau, in compliance with the composition rules indicated in clause 4.1. This commission ensures that: (a) the REC members it appoints have sufficient experience, expertise and are of sufficiently diverse backgrounds to make well-informed decisions regarding the safe and ethical nature of a study and determine whether participants are capable of giving informed consent, (b) the REC members are predominantly researchers, and (c) the REC includes members from different professions.

4.3 Term and renewal

REC members are appointed for 4 years. Half of them are renewed every 2 years. At the first renewal (at the end of the second year), members who wish to put an end to their term are requested to make themselves known. If fewer than half the members wish to terminate their term, the other exiting members are chosen by drawing lots – excluding the bureau members. At each renewal, the Academic Board ensures compliance with REC composition criteria, defined in Articles 4.1 and 4.2 of these regulations.

4.4 Bureau

The REC is governed by a bureau composed of a Chair, Vice-Chair and a Secretary. The Chair and Vice-Chair are elected for 2 years, renewable, by REC members by an absolute majority of votes cast. As far as possible, the Chair and Vice-Chair should not belong to the same institution. The Secretary is appointed by the Chair from among the REC members.

The bureau receives requests for opinions, appoints rapporteurs and allocates the submitted files to them. The bureau can appoint experts from outside the committee to examine a file. In this case, they participate in the REC's work without being entitled to vote. At least once during its term, the bureau re-examines these regulations and the charter that governs them and, if necessary, proposes amendments of these documents to the FUTMP Academic Board.

4.5 Obligations of members

Members of the REC are subject to professional secrecy in view of their duties within this committee. They must not disclose information of any type (scientific or ethical) concerning the projects they examine.

4.6 Loss of committee membership due to non-participation

Any member who has not participated in two consecutive plenary sessions shall be considered to have resigned, unless he has previously informed the Executive Committee of his justified absence. Any member who is unable to participate in a Plenary session and who has not submitted reports on the files assigned to him/her is considered to have resigned, unless he/she has informed the Executive Committee of his/her justified inability to attend upon receipt of the assignment of the files.

5. PROCEDURES

5.1 Referral

Referrals to the bureau of the REC are made by researchers, teacher-researchers and permanent research engineers at FUTMP laboratories. If the research project is conducted by a student, only the research supervisor can refer it to the REC.

The REC comes together no later than two months after submission of a request to examine a file. A file number is allocated to each project submitted, in the format year-order received (e.g.: CER2018-080). The project is submitted according to the procedure indicated on the website. Only REC members have access to the submitted project.

Acknowledgement of receipt is sent by the secretarial office, specifying the date on which the project will be examined.

5.2 Procedures for examination of files

Assessments of an ethical nature are based, in particular, on the following aspects: aim of the research, methods, selection of the persons observed, arrangements for free and informed consent of subjects participating in the research, and for confidentiality and data protection, and risks incurred.

The following points must be complied with when examining the files. REC members declare any interests they may have in the files being processed, prior to their examination. In the case of a conflict, they cannot be rapporteurs or participate in deliberations or voting. Interests include belonging to the same laboratory, involvement in a common research project, the purpose of which is related to the project under examination or in a competing project, common publications, adviser for a public or private organisation, the interests of which may be concerned by the research protocol under examination.

No later than one week after submission of files, the Chair appoints 2 rapporteurs for each of them. The rapporteurs have 2 weeks to prepare their report. A guide is made available to them to draw up their report, indicating the sections that the REC expects to be filled out *as a minimum*. Expert assessments are anonymous.

The project manager(s) may be present at discussions, excluding deliberations. If need be, they can be

represented by colleagues with a doctorate. Students involved in the project may accompany the manager or his/her representative.

The REC returns six categories of opinion following deliberation and, if necessary, a vote: (a) Favourable, (b) Favourable with recommendations (recommendations are detailed in a separate document), (c) Opinion withheld with a request for minor modifications, which will be validated by the Bureau, (d) Opinion withheld with a request for major modifications (to be resubmitted to the REC), (e) Referred to the Committee for the Protection of Individuals with recommendations, and (f) Unfavourable.

Voting takes place in closed session by a majority of the members present. For deliberation and any voting to be valid, the presence of at least one member of the bureau, another member from panel 1 and another member from panel 2 is required.

In the case of requests for opinions that are deemed very urgent by the bureau of the REC, the bureau is considered competent to give an opinion. Such cases must remain rare. In the event of equal votes, the Chair shall have the deciding vote. The opinion is drafted by the bureau and sent to the project leader no later than 15 days after the meeting.

5.3 Re-examination following an unfavourable opinion

In the case of an unfavourable opinion, the project manager has the possibility of submitting the project again. In this case, if necessary, the REC invites the project manager to a hearing. The rapporteurs appointed must be different from those who examined the file when it was submitted the first time.

5.4 Amendment of a project that obtained a favourable opinion

A project that obtained a favourable opinion and that is subject to a new mode of implementation with minor changes to the protocol (additional participants, new measurement, new stimuli, etc.) may be amended, which extends the favourable opinion to the new mode of implementation, without the manager having to resubmit the project. The project leader sends a letter to the bureau of the REC, explaining the changes made to the project and to what extent they do not modify the nature of the protocol. The bureau decides whether or not to accept the amendment. In the case of a refusal, or if the bureau expresses doubt, the REC will examine the amendment.

5.5 Activity report

The Academic Board examines a report on the REC's work presented by its Chair at least once a year. The Academic Board is in charge of updating the internal regulations and the charter following proposals from the Bureau of the REC.

6. ARCHIVES AND PREVIOUS DECISIONS

Following each file examination session, a document is prepared listing the members present with their signatures and an account of the decisions made concerning the projects. These documents are retained by the REC's secretarial office. A confidential register of opinions and of the REC's activity is created and can be consulted at any time by REC members in office. The decisions are made transparent in the form of a public report on the ethics committee's activities.

7. REFERENCE TEXTS

The texts that the ethics committee refers to when determining its opinions notably include the following:

(a) the Huriot-Sérusclat law (French law on the protection of persons consenting to participate in biomedical research), and the Jardé law (French law on research involving human subjects),

(b) the European Charter for Researchers Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data,

(c) the French Data Protection Act (Law 78-17 of 6 January 1978, as amended), and the Regulation EU-2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text of interest for the EEA),

(d) the Code of Ethics of research professions signed by the Conference of Presidents of French Universities and leading public research bodies, the REC charter, the Code of Ethics of the *Société Française de Psychologie* (French Society of Psychology) and of the American Psychological Association, and the *Code de déontologie du psychologue* (French psychologists' Code of Ethics), and

(e) the Helsinki declaration, and the opinions of the CNRS ethics committee (COMETS) and committee for ethical practices (COPé).