

# Regulations Ethical assessment of research by the Research Ethics Review Committee (RERC) of Erasmus School of Health Policy & Management (ESHPM)

as referred to in article 6.2 of the Faculty Regulations.

These Regulations were adopted by the Dean on **15 November** 2021.

These Regulations enter into force on **15 November 2021**.

## Contents

Article 1.1 - Definitions .....	3
Article 2.1 - Objective and responsibilities of the Research Ethics Review Committee .....	4
Article 3.1 – Domain in which the Research Ethics Review Committee operates.....	4
Article 4.1 – Composition and membership of the Research Ethics Review Committee .....	5
Article 5.1 – Recruitment, appointment, reappointment, temporary replacement and dismissal of committee members .....	6
Article 6.1 – Working method/Submission of Application .....	6
Article 7.1 - Decision-making .....	7
Article 8.1 – Obligation of confidentiality and independence .....	8
Article 9.1 – Compensation.....	8
Article 10.1 – Annual Report.....	8
Article 11.1 – Final and transitional provisions.....	8
Article 11.2 – Interpretation .....	9
Article 11.3 – Administration of Regulations.....	9
Article 11.4 - Translation.....	9
Article 11.5 - Short title.....	9
Article 11.6 - Applicable law .....	9

## Article 1.1 – Definitions

1. For the purposes of these Regulations, the terms below are defined as follows:

- <i>Application</i>	A request for approval by a Research Ethics Review Committee of proposed Scientific Research consisting of a Questionnaire and appendices, including, where applicable, (i) an informed consent form; (ii) any other information presented to research participants, and (iii) a data management plan (DMP);
- <i>Committee</i>	See Research Ethics Review Committee;
- <i>Dean</i>	Dean as referred to in Article 9.12 of the Higher Education and Scientific Research Act (WHW); for the purposes of this document, Dean also means the Pro Dean of ESHPM and the rector at ISS;
- <i>Decision</i>	Letter signed by the Chair of the Research Ethics Review Committee when it concerns a positive Final advice of the Committee or by the Dean when it concerns a negative Final advice. The Dean can either endorse the Committee's advice or deviate from it, stating reasons;
- <i>ESHPM</i>	Erasmus School of Health Policy and Management; an institute as described in Ch. 2. Section 1, Art. 2 Institute Regulations Institute Policy & Management in Health Care;
- <i>EUR</i>	Erasmus University Rotterdam;
- <i>EUR policy</i>	What is laid down in the document Principles and requirements pertaining to Research Ethics Review at Erasmus University Rotterdam (EUR);
- <i>Faculty</i>	Faculty as referred to in Article 9.12 of the WHW; for the purposes of this document, Faculty also means ESHPM;
- <i>Faculty regulations</i>	The regulations of the Faculty;
- <i>Final advice</i>	The final advice of the Research Ethics Review Committee;
- <i>Questionnaire</i>	The Research Ethics Review Committee uses a list of questions concerning the objective(s), design, methodology, (statistical considerations) and organisation of a research and mandatory ethical issues as set out in the EUR policy. In addition, subjects may be determined by the Dean. This Questionnaire is adopted by the Dean;
- <i>Regulations</i>	Regulations Ethical assessment of research by the Research Ethics Review Committee (RERC) of Erasmus School of Health Policy & Management (ESHPM )
- <i>Researcher</i>	Individual researchers, including (external) doctoral candidates, guest researchers, part-time researchers and external professionals in so far as they take part in the institution's research or publish their research under the name of the institution <sup>1</sup> ;
- <i>Review</i>	A report of the findings of a member of a Research Ethics Review Committee based on his/her assessment of whether a research

---

<sup>1</sup> Dutch Code of Conduct for Research Integrity 2018, p.10

- proposal complies with the then applicable ethical guidelines on the basis of an Application submitted for this purpose;
- *Scientific research* Scientific research is, in the words of the European Code of Conduct for Research Integrity (revised version, 2017, [also known as: ALLEA code], *"the quest for knowledge obtained through systematic study and thinking, observation and experimentation"*;<sup>2</sup>
  - *Secretary* Support staff who assist Research Ethics Review Committee(s) appointed at Erasmus Research Services;
  - *WHW* The Dutch Higher Education and Research Act;
  - *Written/in Writing* Recorded in writing on paper or 'by electronic means';
2. The terms used in these Regulations have the same meaning as those in the WHW if such terms also occur in the WHW and have not been included in the definitions.
  3. Wherever the masculine form is used in these Regulations, this may also be interpreted as the feminine form and vice versa.
  4. Wherever the singular form is used in these Regulations, this may also be interpreted as the plural form and vice versa.

## Article 2.1 – Objective and responsibilities of the Research Ethics Review Committee

1. The Research Ethics Review Committee (RERC) of ESHPM aims to ensure that Scientific research is conducted in an ethically acceptable manner. Following the Principles and requirements pertaining to Research Ethics Review at Erasmus University Rotterdam (EUR) this implies that all research must be conducted in a manner that respects the safety and rights of participants and that recognises the responsibilities of researchers and of their host and sponsoring organisations." The Committee's task therefore is:
  - a. conducting ethical review of proposed research;
  - b. promoting ethical behaviour of researchers; and
  - c. advising researchers on the ethical aspects of research.
2. Based on the Application, the Research Ethics Review Committee assesses whether the research proposal complies with the then applicable ethical guidelines and issues advice to the researcher (in case of a positive advice) or Dean (in case of a negative advice).

## Article 3.1 – Domain in which the Research Ethics Review Committee operates

1. The ethical review of research applies to research carried out by any ESHPM staff member, including PhD students, postdoctoral researchers, guest researchers and trainees. There

---

<sup>2</sup> Dutch Code of Conduct for Research Integrity 2018, p.7

needs to be a researcher with an appointment or admission at ESHPM who is primarily responsible for the research project, i.e. as the PI (primary investigator).

2. Research that is carried out in the context of education (e.g., MSc thesis research) must be assessed by the supervising lecturer. When research conducted by students falls under a research project from their supervisor, the supervisor is expected to seek ethical clearance for this project as a whole.
3. The key points for assessment by the RERC are, that:
  - A. the human subjects will be well informed about the content of the research activities to be carried out, including how burdensome they will be, their right to withdraw, any possible inconvenience involved and any risks associated with participation, and they will explicitly consent to this ('informed consent');
  - B. the human subjects will be able to withdraw their consent and discontinue participation at any time without any consequences, which must be as easy as to give consent;
  - C. the importance of the research outweighs the burden on the human subjects, the possible inconvenience and any risks associated with participation;
  - D. data is collected and processed in a scientifically responsible manner by taking into account the aspects of confidentiality and anonymity of this data;
  - E. the research activities are carried out in accordance with all relevant GDPR requirements;
  - F. broader ethical concerns are taken into consideration;
  - G. any concerns about the imago of the university as an institution that upholds ethical standards are taken into consideration.
4. If an Application is submitted to the RERC which in the Committee's opinion is covered by the Medical Research (Human Subjects) Act (Wet medisch-wetenschappelijk onderzoek met mensen = WMO), the RERC will state that it is not competent in this case and will refer the applicant to a Medical Research Ethics Committee (Medisch Ethische Toetsingscommissie = METC). Also in case of doubt, the RERC will refer the applicant to a METC.
5. Any Application must be submitted before the data collection of the proposed Scientific Research starts.

#### **Article 4.1 – Composition and membership of the Research Ethics Review Committee**

1. The number of Committee members equals the number of ESHPM's research groups.
2. Each member of the Committee represents one of ESHPM's research groups.

3. Members of the Committee are not bound by any instructions and have a seat on the Committee based on their expertise.
4. The Chair of the RERC is ultimately responsible for the functioning of the Committee.
5. The Chair shall represent the Committee in and out of court. The Chair may (temporarily) delegate this power.
6. The Chair, as well as the Deputy Chair, are either professor or associate professor.
7. All members of the Research Ethics Review Committee have a permanent position at ESHPM.
8. The RERC is supported by a secretary from Erasmus Research Services.

#### **Article 5.1 – Recruitment, appointment, reappointment, temporary replacement and dismissal of committee members**

1. The members, chairs and deputy chairs of the Committee are appointed by the Dean, upon proposal from the Committee and/or research group leaders, for a period of four years.
2. The members, chairs and deputy chairs of the Committee may be reappointed for a period of four years. The Committee shall adopt a retirement schedule.
3. In case of absence, committee members can be temporarily replaced by someone from the same ESHPM research group.
4. Other than at their own request, the Dean may only dismiss the Chair and the members prematurely upon a substantiated proposal of at least two-thirds of the committee members, if they:
  - a. fail to adequately fulfil the obligations arising from membership or chairmanship of the Committee;
  - b. due to their physical or mental condition, must be regarded as having lost their fitness to perform their duties;
  - c. retire.

#### **Article 6.1 – Working method/Submission of Application**

1. Detailed information on ethical guidelines for research can be found via MyEUR. The standard forms and appendices for submitting applications to the RERC can also be found there.

2. Applications for ethics review are submitted via the online tool Ethics Monitor. The Application consists of the following:
  - a. an application form (Questionnaire) in which the applicant is asked to both provide general information about the research and indicate potential ethical issues;
  - b. a Data Management Plan (DMP);
  - c. informed consent form(s); and
  - d. when applicable, any other information presented to participants (information letters, debriefing information, questionnaires, topic lists etc.)
3. In principle, applicants will receive a decision within four weeks of their Application being processed. If necessary, this period may be extended to six weeks. Applicants will be informed of this well in advance. If the RERC provides the applicant with instructions for changes to the Application, the procedure may take longer. The applicant always receives a Written response from the Secretary of the Committee.
4. The Application will be reviewed by (at least) two members of the RERC, the Privacy Officer, and the Research Data Steward. The RERC will decide whether or not a research proposal shows to a sufficient degree that the ethical rules for conducting research with human subjects will be complied with. Before issuing its opinion, the Committee may either ask the applicant for further information or clarification.
5. If the RERC is of the opinion that a research project meets all the ethical criteria, the Committee issues a Declaration of No Objection. If the RERC is of the opinion that one or more ethical criteria have not been sufficiently met, it advises the researchers on the measures to be taken in order to comply with the requirements. In the unlikely case that feedback has not been adequately addressed, the applicant will not receive ethical clearance. The Committee will then advise the Dean, who will decide whether the research project can start.
6. In all cases, the researcher remains responsible for the application of ethical rules, also after approval by the RERC.

## Article 7.1 – Decision-making

1. Valid Decisions can only be taken when agreement has been reached based on the steps described below.
2. If the Chair or a member is in any way personally involved in a research proposal submitted for review, he or she will not take part in the deliberations and decision-making on the Application, either in or outside the meeting.
3. Any Application is reviewed independently by two members of the Ethics Committee.
4. The Secretary assesses whether the members, contradict each other in their review. If this is the case, the Secretary will consult with these members of the Committee in order to

arrive at a review without contradictions. If this does not succeed, the Secretary shall convene a meeting with the full Committee.

5. The aim is to achieve unanimity when making decisions.
6. Decisions can only be taken by a simple majority of the number of valid votes cast.
7. In the event of an equal distribution of votes, the Chair shall have the casting vote.
8. Decision-making takes place orally, unless the Chair, whether or not at the request of one or more members present, decides to have the vote taken in writing.
9. The member who takes a minority view on a decision may ask the Secretary to make explicit mention thereof in the report.

### **Article 8.1 – Obligation of confidentiality and independence**

1. All EUR employees act in accordance with art. 1.16 Confidentiality of the Collective Labour Agreement of Dutch Universities – VSNU.
2. In case an External advisor is involved, a nondisclosure agreement needs to be asked from the HR department.

### **Article 9.1 – Compensation**

1. The EUR regulations reimbursements Research Ethics Review Committees applies.

### **Article 10.1 – Annual Report**

1. The Committee reports annually to the Daily Board of ESHPM on its activities.

### **Article 11.1 – Final and transitional provisions**

1. These Regulations may be amended and adopted by a simple majority of the Members of the Committee, after which the amendment(s) shall be submitted to the Dean for approval.
2. These Regulations were adopted at the meeting of the Research Ethics Review Committee of 26 September 2021 and were approved by the Daily Board at its meeting of 15 November 2021 and enter into force on the same day.

### **Article 11.2 – Interpretation**

1. In cases relating to matters provided for in these Regulations that are not covered by these Regulations, or in cases where these Regulations may be interpreted in several ways, the decision shall rest with the Dean.

### **Article 11.3 – Administration of Regulations**

1. These Regulations are administered by the Dean.

### **Article 11.4 – Translation**

1. If these Regulations are translated and any conflict arises between the translation and the Dutch version, the Dutch version will prevail.

### **Article 11.5 – Short title**

1. These regulations are referred to as: Regulations Ethical assessment of research by the Research Ethics Review Committee (RERC) of Erasmus School of Health Policy & Management (ESHPM)

### **Article 11.6 – Applicable law**

1. These Regulations are governed solely by Dutch law.