Principles and requirements pertaining to Research Ethics Review at Erasmus University Rotterdam (EUR)

0. Context

The Netherlands Code of Conduct for Research Integrity, 2018, in particular its clause 4.18, makes it necessary for Dutch universities to assure full compliance of research projects with ethical requirements, among other things. That clause reads as follows:

"Undertake ethical reviews where necessary; for example, by setting up one or more ethical committees and providing them with adequate support. These committees can provide researchers with binding or non-binding advice on issues such as the use and treatment of patients, human and animal test subjects, the possible risks of publishing data, the use of human tissue, risks to the environment or cultural heritage and potential conflicts of interest."

This document addresses how research ethics review will be organized at EUR and is concerned with the elements of the Code of Conduct related to ethics review.

1. Research Ethics Review at EUR

Principles and requirements pertaining to research ethics review at EUR have as its objective that each individual EUR researcher performs research[1] in an ethically acceptable manner: "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"[i]. Furthermore, each researcher will have the possibility to have all these aspects properly assessed.

"Compliance with the Code of Conduct is both an obligation and an opportunity. Properly implementing Research Ethics Review Committees with accompanying procedures and adequate communication of ethical obligations to all researchers, will augment the capabilities of scientists to:

•   perform truly independent research;
•   ensure that they properly take into account the interests of their research subjects;
•   systematically consider possible consequences of their research and make deliberate choices on this.

A strong reputation of the EUR in this respect will increase our opportunities to become involved in ground-breaking research, to get access to unique data and to create more societal impact."[ii]

The principles and requirements addressed below define along which lines EUR organises research ethics review. The corresponding roles, responsibilities and tasks are addressed in paragraph 5.

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[1] Research throughout this document is seen as "the quest for knowledge obtained through systematic study and thinking, observation and experimentation", The European Code of Conduct for Research Integrity (ALLEA-code), 2017

2. Principles

i. Research ethics review focuses on the research design and will take place before the research starts;

ii. Ethical issues relating to research integrity do not fall within the remit of Research Ethics Review Committees[2];

iii. Research conducted by EUR researchers[3] that involves:

1. Human beings[4];	5. Potential misuse of research results[iii];
2. (Special categories of) personal data;	6. Potential conflict of interest[iv];
3. Non-EU countries[5];	7. External stakeholders, among which funding organisations[v]
4. Environment, health & safety issues, including potential harm to researchers;	

needs to undergo ethical review by a relevant and independent committee; recruitment practice should take this into consideration[6];

iv. Research conducted by EUR researchers that falls under the Dutch Medical Research Involving Human Subjects Act needs to undergo ethical review by the Medical Ethics Review Committee (METC). This is the case[vi] when:

1. Medical research is proposed in which people are subject to acts; and
2. Rules of behaviour are prescribed to people.

Both the METC and EUR Research Ethics Review Committees can evaluate whether a research proposal falls under this Act. Studies that do not fall under this Act can be reviewed by an EUR Research Ethics Review Committee.

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[2] Since research integrity is about the behaviour and conduct of the researcher rather than the research plans and activities themselves, matters of research integrity are generally handled by other committees than those that perform ethics assessment of research and innovation projects, proposals and practices; (ftp://ftp.cencenelec.eu/EN/ResearchInnovation/CWA/CWA1714501.pdf, p. 17).

[3] Individual researchers, including PhD students (whether or not they are employed as such by their university) and visiting researchers, part-time researchers or external professionals insofar as they participate in research by or at the institution or disclose their research in its name (Netherlands Code of Conduct for Research Integrity, 2018, paragraph 1.3, article 9), including researchers appointed at the limited liability companies affiliated with EUR.

[4] Different methodologies fall under this umbrella, including e.g. internet research and engaged research*

* Engaged research describes a wide range of rigorous research approaches and methodologies that share a common interest in collaborative engagement with the community and aim to improve, understand or investigate an issue of public interest or concern, including societal challenges. Engaged research is advanced with community partners rather than for or about them. (www.rri-tools.eu/-/how-to-guide-a-framework-for-engaged-research).

[5] Research involving non-EU countries concerns research activities which are conducted, partially or wholly, in a non-EU country, participants or resources come from a non-EU country and material is imported from or exported to a non-EU country. Being outside the reach of European laws and standards, such research can raise specific ethical issues (particularly in developing countries), such as: exploitation of research participants, exploitation of local resources, risks to researchers & staff, research that is prohibited in the EU. (http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf, p. 25)

[6] In many situations, independence will be essential in providing fair ethical judgements and expertise and recruitment practice should take this into consideration. After: Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects, 2a, p3.

v. Research conducted by EUR researchers that involves:

1. Animals

needs to undergo ethical review by the Animal Welfare Body (Instantie voor Dierenwelzijn (IvD)).

vi. Schools[7] can define issues that they would like to see checked in addition;

vii. Schools decide which questions will be asked to be able to perform good ethics review.

viii. A dedicated combination of reviewers performs the review. Schools decide what will be the consecutive steps[8] for each Research Ethics Review Committee in case the dedicated combination of reviewers does not succeed in issuing a shared advice.

ix. Research Ethics Review Committees evaluate whether the research proposal respects the safety and rights of participants and recognises the responsibilities of researchers and of their host and sponsoring organisations[vii] and hereto consider national and international principles pertaining to the discipline and EUR principles and requirements;

x. Research Ethics Review Committees advise the Dean[9] regarding ethics applications of EUR researchers; the Research Ethics Review Committee receives the mandate of the Dean to issue the approval letter when the advice is positive; when the advice is negative, the Dean decides. A positive decision by the Dean following up upon the negative advice of the Research Ethics Review Committee requires a relevant motivation;

xi. An interested party (among which the applying researcher(s)) can file objections to the decision of the Dean with the Advisory Committee for Notices of Objections; The Advisory Committee will advise the Dean about the decision on the objection[viii]; Consequently, an interested party may appeal to the district court against the decision on the objection[ix].

xii. Researchers act in accordance with the approved application; any subsequent substantial amendments that touch upon one of the topics mentioned above should be reported and explained to the Research Ethics Review Committee;

xiii. Advice to be compliant with relevant methodological standards[10] and policy and guidelines in the domains of data management and privacy law will be provided by the relevant support services to which members of the Research Ethics Review Committees can refer.

Student research

xiv. Schools at least[11] define the boundaries within which students can conduct research and provide students with the appropriate guidelines;

xv. In case it is decided that students also submit applications for ethics approval, a separate procedure for objections needs to be put in order based on art. 7.63a of the WHW. In that case, the Advisory Committee for Notices of Objections will act as the dispute advisory committee as referred to in article 7.63a of the WHW.

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[7] Where Schools is used it includes ISS.

[8] e.g. the full Research Ethics Review Committee decides based on majority vote after deliberation.

[9] Where Deans is used it includes the Pro-dean at ESHPM and the Rector at ISS.

[10] Netherlands Code of Conduct for Research Integrity, 2018, preamble: "Research in the sciences and the humanities derives its status from the fact that it is a process governed by standards. That normativity is partly methodological and partly ethical in nature …".

[11] Schools may declare the ethics review procedure applicable to (Research Master) students.

Specifics

xvi.   In case the research is conducted in a country other than the Netherlands, the principal investigator is responsible for ensuring that the research is conducted with due regard for local laws, habits and customs.[x] An ethical review by a local committee may be necessary;

xvii.   Researchers apply to (one of) the Research Ethics Review Committee(s) of the School they work at. If, for any reason, the researcher (needs to) submit(s) an application to a Research Ethics Review Committee of a different School, the Dean of the School the researcher is working at takes the final decision based on the received advice;

xviii.   In case of cooperation between researchers of different Schools, Deans of all involved Schools sign the final decision.

xix.   When research has received approval from a non-EUR Research Ethics Review Committee, Deans take a decision based on the advice of the external Committee;

xx.   Researchers (principal investigators) who will be *leading* a collaborative programme need to apply for approval for the approach towards ethics and implementation thereof within the programme *and* are responsible for collecting ethics approval letters by leaders of the research projects that will be conducted within the programme;

xxi.   Researchers who are going to conduct research within the context of a collaborative programme need to apply for approval for the research project they lead or when they participate in projects led by others submit the advice of the external Research Ethics Review Committee to the Dean who will take a decision.

xxii.   Research that has received prior approval from an EUR Research Ethics Review Committee based on a research proposal that is highly similar to the new application only needs to be reviewed with regard to the changes.

3. Requirements

i.   All applications for ethical review, including if applicable a Statement of Confirmation for compliance with GDPR, a Data Management Plan provided with a positive advice from a relevant advisory body or person, an approved informed consent form, other relevant documents and the Letter of Approval of the Research Ethics Review Committee must be stored in an IT environment supported by EUR;

ii.   EUR researchers sign for being fully aware of and adhering to the Netherlands Code of Conduct for Research Integrity 2018 in the context of the ethical review procedure[12];

iii.   On top of this, researchers performing research in the Social and Behavioural Sciences[13] also sign for being fully aware of and adhering to the Code of Ethics for research in the Social and Behavioural Sciences involving human participants, 2018 in the context of the ethical review procedure.

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[12] This concerns a reconfirmation of what has been stated in the labour contract; the professors agreement; the unpaid employee agreement and the hospitality agreement.

[13] This national code has been signed by ESSB.

4. Infrastructure

    i.   The Erasmus Medical Centre provides for a Medical Ethics Review Committee;

    ii.   EUR Schools together provide for Research Ethics Review Committees that review applications and hereto consider national and international principles pertaining to the discipline and EUR principles and requirements;

    iii.   Limited liability companies agree upon conditions for cooperation with affiliated Schools.

    iv.   Tasks and responsibilities related to research ethics (review) are assigned to Deans and Research Ethics Review Committees, in the Schools' Regulations [Faculteitsreglementen];

    v.   EUR provides for a general EUR policy framework which leaves room for discipline- and School related specifics;

    vi.   EUR provides for an Advisory Committee for Notices of Objection [Adviescommissie voor de Bezwaarschriften] and a proper procedure; Each School will provide one member for the Advisory Committee for Notices of Objection.

    vii.   EUR provides for support to the Research Ethics Review Committees and the Advisory Committee for Notices of Objection;

    viii.   EUR provides for (a) fitting and safe IT application(s) to support the ethics review procedures that will be used throughout university;

    ix.   EUR provides for training in research ethics for researchers, members of the Research Ethics Review Committees, the Advisory Committee for Notices of Objection and their support staff;

    x.   EUR will set-up a supportive communication structure;

    xi.   EUR facilitates sharing available knowledge and best practices;

    xii.   EUR monitors compliance with the accepted policy Principles and requirements pertaining to Research Ethics Review at Erasmus University Rotterdam (EUR) by way of annual meetings between the Rector Magnificus and chairs of the Research Ethics Review Committees.

5. Roles, responsibilities and tasks

Annex 2 to the Roadmap EUR Implementation Netherlands Code of Conduct for Research Integrity lists responsibilities in relation to scientific integrity. Below responsibilities and tasks pertaining to research ethics review are described in more detail.

	EUR EXECUTIVE BOARD
Annex 2	The Executive Board (EB) bears final responsibility for research policy and research integrity and is responsible for the conditions to promote research integrity and professionalism.
Code of Conduct	More specifically, the EB bears final responsibility for the duties of care as stated in the Netherlands Code of Conduct for Research Integrity. The Code sets out duties of care in chapter 4.
EUR embedding	Policy and other related EUR guidelines, will contribute to: ▪ empowering organisational units ▪ providing appropriate means and resources for research support operations ▪ the upkeep of services and providing infrastructures ▪ employee education and monitoring practices ▪ providing an open, safe and inclusive research culture in which researchers can discuss the standards for good research practices.
	The Executive Board appoints members of the Advisory Committee for Notices of Objection after nomination by the Deans.
	SUPPORT SERVICES AT EUR LEVEL
EUR embedding	At central EUR level, one level below the Executive Board, the responsibilities for the duties of care lie with Academic Affairs, Erasmus Research Services, Chief Information Officer office and Legal Protection.
	ACADEMIC AFFAIRS, TOGETHER WITH ERASMUS RESEARCH SERVICES
Code of Conduct	• Raise awareness about research integrity within the organization and, where necessary, provide or facilitate training courses for researchers, support staff, research leaders and research managers. (par. 4.2, art. 1) • Provide clear instructions, protocols and other means to support researchers and to help them understand what constitutes good research practice within their discipline(s) and institution. (par. 4.3, art. 8)
	ERASMUS RESEARCH SERVICES
Code of Conduct	See under Academic Affairs
EUR embedding	• Prepare an implementation plan, including a budget. • Coordinate implementation of the approved implementation plan. • Liaise with relevant stakeholders. • Prepare decision making for Research Ethics Review Committees (in the role of secretary). • Develop training and communication.

	Within ERS these tasks are assigned to the Coordinator Research Ethics Review and several secretaries (some performing under a School).
	CHIEF INFORMATION OFFICE
EUR embedding	Fit of the Ethics Review process within the EUR Research architecture.
	LEGAL PROTECTION
EUR embedding	Provide support to the Advisory Committee for Notices of Objections.
	SCHOOLS
	DEANS
Annex 2	Deans bear final responsibility for the School's research policies as well as research integrity and are responsible for its embedding.
Code of Conduct	• Ensure compliance with all relevant statutory regulations, codes of conduct, instructions and protocols. (par. 4.3, art. 6) • In the event of an investigation into alleged research misconduct, make all relevant documents available for verification subject to the confidentiality safeguards established by the Executive Board. (par. 3.2, art. 12a)
EUR embedding	• Embed good ethics review in the Schools and set up one or more Research Ethics Review Committees. • *Principles x, xvii, xviii, xix; xxi*: Take formal decisions on whether research proposals can be conducted as proposed 1) in response to a request of the School's Research Ethics Review Committee or 2) when an ethics review has been performed by a Research Ethics Review Committee outside of the School. • *Principles vi, vii*: Make sure a decision taking procedure is in place to define ethics issues that the School would like to see checked in addition to the compulsory ones (principles iii – v) and to decide which questions need to be asked to be able to perform good ethics review. • *Principle viii:* Make sure that for each Research Ethics Review Committee there is a description of the review - and decision making procedure available. • *Principles xiv.:* Define the boundaries within which students can conduct research and provide students with the appropriate guidelines.
	Deans appoint members of the School's Research Ethics Review Committees and mandate the Research Ethics Review Committee(s) to take decisions which concern approval. *Deans nominate members for the Advisory Committee for Notices of Objection.*

	RESEARCH DIRECTORS
Annex 2	Research directors are responsible for the training and supervision of PhD students and other academic staff involved in the School's research programmes.
Code of Conduct	• Raise awareness about research integrity within the organization and, where necessary, provide or facilitate training courses for researchers, support staff, research leaders and research managers. (par. 4.2, art. 1) • Ensure ethical reviews are conducted where necessary. (par. 3.2, art. 13) • Ensure clear instructions, protocols and other means to support researchers are provided and to help them understand what constitutes good research practice within their discipline(s) and institution. (par. 4.3, art. 8)
EUR implementation	• Responsibilities and tasks depend on the mandate received from the Dean.
	EDUCATIONAL DIRECTORS
Annex 2	Educational directors are responsible for the content of study programmes as well as for the training and supervision of BA/MA students.
Code of Conduct	• Within an educational setting, the Code is meaningful as an object of study and in training courses. Scientific and scholarly research by students therefore falls within its normative framework (chapters 2 and 3). As long as that research is conducted only in an educational context and does not result in publications other than a published thesis, however, non-compliance with the standards of this Code cannot result in a complaints procedure as described in section 5.4 or in imposing sanctions as described in section 5.3. (par 1.3, art 11)
EUR embedding	• Responsibilities and tasks depend on the mandate received from the Dean.

	RESEARCHERS
	By researchers we mean "individual researchers, including PhD students (whether or not they are employed as such by their university) and visiting researchers, part-time researchers or external professionals insofar as they participate in research by or at the institution or disclose their research in its name."[14]
Annex 2	Researchers are responsible for research integrity and professionalism at the individual level.
Code of Conduct	• The Code provides both (a) methodological standards (as to what a good researcher does) and (b) ethical standards (as to what a researcher with integrity does). • The principles addressed in the code are honesty, scrupulousness, transparency, independence and responsibility. Researchers who are not guided by these principles risk harming both the quality and the trustworthiness of research. (Preamble) Responsibilities which typically fall within the remit of Research Ethics Review Committees are presented in bold. Researchers: • Are expected to internalize and be guided in their research activities by the educational and normative framework provided in chapters 2 and 3. (Preamble, I) • **Take into consideration the interests of any humans and animals involved, including test subjects, as well as any risks to the researchers and the environment, while always observing the relevant statutory regulations and codes of conduct.** (par. 3.3, art. 26) • Enter into joint research with a partner not affiliated with an institution which has adopted this or a comparable Code only if there is sufficient confidence that their own part of the research can be conducted in compliance with this Code and the joint research results meet generally accepted principles of integrity in research. (par. 1.2, art. 8) • In research with external partners, make clear written agreements about research integrity and related matters such as intellectual property rights. (par. 3.2, art 9) • **If the research is conducted on commission and/or funded by third parties, always specify who the commissioning party and/or funding body is.** (par. 3.2, art 7) • Accept only research assignments that can be undertaken in accordance with the standards in this Code. (par. 3.2, art 14) • **Be open and complete about the role of external stakeholders, commissioning parties, funding bodies, possible conflicts of interest and relevant ancillary activities.** (par. 3.4, art 44)

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[14] Netherlands Code of Conduct for Research Integrity, 2018, paragraph 1.3, article 9

	• **Be transparent about the method and working procedure** followed and record them where relevant in research protocols, logs, lab journals or reports (par. 3.4, art 35; see also[15])
EUR embedding	• *Principles iii, iv, v, xvii, xxii*: Apply to the appropriate EUR Research Ethics Review Committee(s) when one of the presented ethics topics occurs; • *Principle xii*: Act in accordance with the approved application; report and explain any subsequent substantial amendments that touch upon one of the topics mentioned under principle iii, iv and v to the Research Ethics Review Committee. • *Principle xvi*: In case the research is conducted in a country other than the Netherlands, the principal investigator is responsible for ensuring that the research is conducted with due regard for local laws, habits and customs. • *Principles xix, xxi*: when ethics approval has been received by an external Research Ethics Review Committee, submit the complete file to the Dean for a formal decision.
	RESEARCH LEADERS
	By research leaders we mean: "supervisors, principal investigators, research directors and managers insofar as they help determine the design and conduct of research."[xi]
Code of Conduct	Research leaders (as a group) are expected to: • Ensure that new researchers and PhD students are supervised by suitably qualified persons. (par. 4.2, art. 4) • Take appropriate measures to prevent non-compliance with the standards. For example, monitor the quality and intensity of the supervision of starting researchers such as PhD students as well as the composition of PhD committees. (par. 4.3, art. 9)
	• *Principle xx*: when leading a collaborative programme apply for approval for the approach towards ethics and implementation thereof within the programme and collect ethics approval letters by leaders of the research projects that will be conducted within the programme.
	STUDENTS
Code of Conduct	Students are expected to internalise and be guided in their research activities by the educational and normative framework provided in chapters 2 and 3. (Preamble, I)

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[15] https://globalhealthtrainingcentre.tghn.org/elearning/modular-courses/ - Essential elements of ethics: Protocol authors should address certain ethical issues in the design of studies and document their rationale in a section of the protocol that will be easily understood by review boards and investigators

	(SCHOOL's) RESEARCH ETHICS REVIEW COMMITTEES
Code of Conduct	Research Ethics Review Committees can provide researchers with binding or unbinding advice on issues such as the use and treatment of patients, human and animal test subjects, the possible risks of publishing data, the use of human tissue, risks to the environment or cultural heritage and potential conflicts of interest. (par. 4.6, art. 18)
EUR embedding	• *Principle x*: At EUR Research Ethics Review Committees receive the mandate of the Dean to provide researchers with the decision on a positive advice (approval). In case the Research Ethics Review Committee does not approve of the revised application it requests a formal decision from the Dean.
	Members of the Research Ethics Review Committees are appointed by the Dean and receive the mandate to provide researchers with a decision in case it concerns an approval.
	MEMBERS OF RESEARCH ETHICS REVIEW COMMITTEES
Code of Conduct	Members of Research Ethics Review Committees are expected to: • Conduct ethical reviews where necessary. (par. 3.2, art. 13)
EUR embedding	• *Principle viii:* Conduct ethical reviews in accordance with a predefined procedure. • *Principle ix:* Consider national and international principles and requirements pertaining to the discipline, EUR principles and requirements. • Engage in discussing (mostly in writing) the application with the co-reviewer(s) and the lead researcher. • *Principle x*: Provide advice to EUR researchers following up on an application.
	Members of the Research Ethics Review Committees are appointed by the Dean of the relevant organizational unit.
	CHAIRS OF RESEARCH ETHICS REVIEW COMMITTEES
EUR embedding	Chairs of Research Ethics Review Committees are expected to: • Chair meetings of the full Research Ethics Review Committees, if applicable. • Sign for approved applications. • Be the first contact person for the secretary in case no agreement can be reached on the advice regarding an application.
	SECRETARIES OF RESEARCH ETHICS REVIEW COMMITTEES
EUR embedding	The secretaries are expected to: • Support the Research Ethics Review Committees. • Monitor compliance with existing procedures and propose modifications of procedures.

	ADVISORY COMMITTEE FOR NOTICES OF OBJECTIONS
EUR embedding	Members of the Advisory Committee for Notices of Objections are expected to: • *Principe xi:* Advice the Dean when an interested party objects to a decision by the Dean regarding an application for ethics approval of a research proposal.
	Members of the Advisory Committee for Notices of Objections are appointed by the Executive Board. *The Committee receives support from Legal Protection.*

Endnotes

[i] https://globalhealthtrainingcentre.tghn.org/elearning/modular-courses/
[ii] Annex 3 to the Roadmap EUR Implementation Netherlands Code of Conduct for Research Integrity
[iii] Themes have been derived from:
http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf - Ethics Self-Assessment H2020 Funding programme; Furthermore, the issues 2. Human beings; 5 Animals; 7. Environment, health & safety issues are addressed in Netherlands Code of Conduct for Research Integrity, 2018, paragraph 3.3, article 26)
[iv] Netherlands Code of Conduct for Research Integrity, 2018, paragraph 3.6, article 55
[v] Netherlands Code of Conduct for Research Integrity, 2018, paragraph 3.2, article 8
[vi] https://www.ccmo.nl/onderzoekers/wet-en-regelgeving-voor-medisch-wetenschappelijk-onderzoek/uw-onderzoek-wmo-plichtig-of-niet
[vii] - Research Ethics online training: https://globalhealthtrainingcentre.tghn.org/elearning/modular-courses/
[viii] Based on art. 7:13 Awb
[ix] Based on art. 8:1 Awb
[x] Derived from Code of Ethics for research in the Social and Behavioural Sciences Involving human participants, B7, p.6
[xi] Netherlands Code of Conduct for Research Integrity, 2018, paragraph 1.3, article 9