Protocol

Research Ethics Committee Faculty of Science
Radboud University Nijmegen

Task and mandate of the committee

The task of the Research Ethics Committee (REC) of the Faculty of Science of Radboud University is to assess whether ethical principles and guidelines are observed in scientific research projects conducted at the Faculty of Science. The REC follows a bottom-up procedure, which means that it performs assessments of research projects only upon request by principal investigators / project leaders of the projects involved. Whether a research project is eligible for ethical assessment, and whether an abridged or full procedure is applicable, is determined in a pre-selection procedure (further specified below).

The responsibility for the ethical appropriateness of the design and execution of the research, at any stage of a research project, both before and after ethical approval by the REC, lies with the researcher or PI who is responsible for the research project. The REC performs assessments of projects; its task is not to monitor whether ethical principles are actually observed in practice.

Besides project assessment, upon request by the Faculty Board, the REC may also provide advice on policy-related or strategic issues that relate to research ethics.

The assessment of research in the context of education (for instance: master theses) is not the principal task of the REC, but requests for such assessments may be taken into consideration if there is a convincing case.

When to apply for ethical assessment?

In the following situations, ethical assessment by the REC can be requested:

- If a funding agency requires ethical assessment, either before a proposal may be submitted, or after an application for funding has been granted;
- If a journal or publisher requires ethical assessment of research before a scientific paper may be submitted or published;
- If an institutional policy, such as a Research Data Management (RDM) policy, prescribes that ethical assessment is required;
- If a researcher has another reason to think that ethical assessment of intended research is necessary.

In any case, ethical assessment only takes place before the research starts; the REC does not retroactively assess research.

Research that is not eligible for assessment by the REC

The REC does not assess research that falls under the Medical Research Involving Human Subjects Act (WMO). This type of research needs to be assessed by an accredited Medical Research Ethics Committee. Furthermore, the REC does not assess research with animals; this is done by the Radboud University Animal Ethics Committee (RUDEC). More information about whether research
falls under the WMO can be found on the website of the Central Committee on Research Involving Human Subjects (CCMO). Information on the RUDEC can be found on the website of the RUMC.

**Ethical principles and guidelines**

The point of departure for the REC’s assessment procedure is the *Netherlands Code of Conduct for Academic Practice* (VSNU), in which relevant principles are identified (honesty, reliability, verifiability, impartiality, independence and responsibility). In accordance with this code, special attention is given to (1) informed consent (respect for autonomy and privacy of human research subjects), (2) risks for participants and responsibilities of researchers, (3) responsible data management, especially management of personal data; and (4) strategies for dealing with unexpected findings. More information on the code can be found on the website of the VSNU.

**Application and assessment procedure**

Applications for ethical assessment can be submitted by e-mail to the secretary of the committee. Applications need to include the following:

- A research plan that at least describes the goal, questions and methodology of the research;
- A short memorandum that explains what are the main ethical issues in the proposed research, and how these issues will be dealt with;
- If the research involves human respondents or participants, documentation concerning the informed consent procedure;
- A data management plan (DMP).

After submission of these documents, the REC chair and secretary assess whether the application is complete and admissible. If this is the case, the chair and secretary decide whether the request will be handled via an abridged procedure, or requires a full assessment procedure (which means: assessment by the whole committee during a formal meeting).

An abridged assessment procedure may be followed in the case of highly standardized research that, according to the judgement of the chair and secretary, does not raise specific ethical issues that need to be discussed by the full committee. If the chair and secretary intend to provide ethical approval via an abridged procedure, the members of the REC will be informed about this, and are invited to comment on this intended approval.

If one or more committee members have objections against this intended approval via the abridged procedure, or if there are ethical issues that need to be discussed by the full committee, the application is handled in a full assessment procedure. The full assessment procedure entails that the proposed research, including all relevant documents that have been provided, will be assessed by the REC in a committee meeting.

The secretary of the REC informs the applicant about the decision of the REC. This may be (a) ethical approval; (b) a request for adjustments in the proposed project or the provided documents (for instance: revision of the informed consent procedure); (c) a request for more information / clarification; or (d) rejection.

After ethical assessment, it is the applicant’s responsibility to comply with the REC’s decision and, in the case of ethical approval, to conduct the research in accordance with the approved procedures. The REC does not monitor such compliance. Not observing the REC’s decision or the approved
procedures may be considered as scientific misconduct, for which dedicated regulations and provisions are in place at Radboud University.

Requirements to documents

The documents related to the ethical assessment request, including DMPs and informed consent procedures, must comply with the research data management (RDM) policy of the applicant’s research institute. The REC does not perform in-depth assessments of DMPs, but requires a DMP as part of an assessment request, to assess how data management-related ethical aspects are dealt with in the proposed research. The Faculty’s institutes have RDM policies that contain requirements to DMPs. Help in drafting a DMP can be given by the institute’s data steward or by the university’s RDM support team (www.ru.nl/rdm). The RDM policy of the research institute may also contain requirements concerning informed consent procedures.

The informed consent procedure should mention that complaints or concerns regarding the research can be directed to either the responsible researcher, or to a confidential advisor. Names and contact details of these persons should be included in the documents. Information that is provided as a basis for a consent decision should be neutral and not aimed at convincing people to participate.

The website of the REC contains links to more information on informed consent procedures.

Composition of the committee

The REC consists of members from several Research Institutes within the Faculty of Science, as well as members representing ethical, legal, and data management expertise. Committee members are appointed by the Board of the Faculty of Science. The current composition of the committee can be found on the REC’s website.

Frequency of meetings

The committee in principle schedules three meetings each year, but may cancel, add or reschedule meetings, depending on the number and urgency of assessment requests.

Archiving and reporting

Documents submitted to the REC by applicants, correspondence from the REC to applicants, and minutes of the REC, are filed in the Faculty of Science archive.

The secretary and chair prepare an annual report on the REC’s activities, and offer this report to the Faculty Board. This report does not contain personal data of applicants. The annual report of the REC serves as input for the Faculty’s annual report.

Complaints about the REC

Applicants can raise concerns or objections regarding the REC either to the Secretary of the REC, or to Ir. Jan-Jetze Zijlstra (adjunct secretary, Faculty Board, Faculty of Science).