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 in advance; its task is not to monitor whether ethical principles are actually observed in practice during the execution of the project.

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

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?

Typical forms of research for which ethical assessment is recommended:

- Research involving humans that is not subject to the Medical Research Involving Human Subjects Act (WMO);
- Research involving personal data;
- Research for which there is a potential risk of misuse of the results.

In addition, 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;
- a journal or publisher requires ethical assessment of research before a scientific paper may be submitted or published;
- an institutional policy, such as a Research Data Management (RDM) policy, prescribes that ethical assessment is required.

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. In case of doubt whether or not the research falls under the WMO, the applicant is advised to consult the Medical Research Ethics Committee first.

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 REC's assessment procedure is based on the following criteria:

- Scientific relevance: the research should be scientifically relevant.
- Proportionality: the expected gains are proportional to the expected efforts.
- Methodological soundness: the applicant uses the correct research methods for the research problem at hand.
- Risks and safety: the research participants should be as safe as possible and exposed to the least amount of risk as possible.
- Execution: the research and experiments should be executed by qualified personnel.
- Data management: the relevant procedures regarding data management should be taken into account. These pertain to, amongst others, data storage, data collection and access to the research data.
- Autonomy: the autonomy of research participants should be respected.

Application and assessment procedure

Applications for ethical assessment can be submitted by e-mail to the secretary of the committee. Applications consist of a completed application form; the form can be found at the website of the REC. This form also helps to determine which additional documents have to be submitted.

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, regular or extended assessment procedure, as explained in the following paragraphs.

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. In the case of a resubmission, the chair and secretary can approve an application if the applicant has revised the earlier submission in accordance with the committee's comments and suggestions for modifying the application.

If one or more committee members have objections against this intended approval via the abridged procedure, a *regular assessment procedure* will be started. In this case, two reviewers from the ethical committee will be selected to evaluate the application. If there are ethical issues that need to be discussed by the full committee, the application is handled in an *extended assessment procedure*. The extended assessment procedure entails that the application will be assessed by the REC in a committee meeting.

The default option is a regular assessment procedure.

Both the regular and the extended procedure can have two outcomes:

1. The reviewers require modifications to the application. In this case, the application is rejected and the applicant is informed about the changes that need to be made in order for the application to be approved. The applicant can then improve the application and submit the improved version with an explanation of how the application has been improved. This resubmission then follows the same route as first submission (first judgement by chair and secretary, then a decision on the procedure, etc.)
2. The application is approved.

The secretary of the REC informs the applicant about the decision of the REC.

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.

Requirements to documents

The documents related to the ethical assessment request, including Data Management Plans (DMP's) 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.

Prior to submission of the DMP to the REC, the DMP should have been reviewed by RDM support. This can be done via the RIS tool for creating DMPs. More information can be found in the application form.

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 (https://www.ru.nl/science/research/about-our-research/ethics-committee/) 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

Approved applications, letters of approval, minutes of the REC, and other documents deemed worthy of archiving 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 Lisette Maat LLB (adjunct secretary of the Faculty Board, Faculty of Science, FNWI).