| Regulations of the Faculty Ethics Review Board (FERB)            |
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| Faculty of Social and Behavioural Sciences of Utrecht University |
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Version: December 2023

These regulations were adopted unchanged by the Faculty Board on January 25, 2024.

#### Introduction

The Faculty Ethics Review Board (FERB) has been established by the Faculty of Social Sciences' administration since 2014. The aim of the Faculty Ethics Review Board is to promote a sense of standard ethics among, and responsible action by, faculty staff and students regarding the rights, safety and welfare of participants in that scientific research.

As of September 1<sup>st</sup>, 2022, the board has also established a Faculty Integrity Policy Committee (FCI) of which FERB is a part. The FCI promotes knowledge about scientific integrity.

The Faculty Integrity Policy Committee advises the dean on all policy matters involving (scientific) integrity. The FCI does not deal with complaints or suspicions about violations of scientific integrity. This is the explicit mandate of the (central) university Committee on Scientific Integrity.

The aim of the Faculty Integrity Policy Committee is to set frameworks in the field of scientific integrity for social scientific research, and to promote knowledge and awareness of standards in this field among staff of the Faculty of Social Sciences.

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#### **Competence of the FERB**

The general point of departure is that the Faculty Board assumes that all the researchers at the Faculty of Social and Behavioural Sciences are committed to conducting research in an ethically responsible manner in accordance with the prevailing conduct and professional codes and legislation (national, European, and international).

As of May 25th 2018, the General Data Protection Regulation (GDPR) has come into force – posing new demands on any organization that processes personal data. Considering the nature of its scientific focus, many of the research conducted at the faculty of Social and Behavioural Sciences is not only subject to the national code for academic practice of the *Universiteiten van Nederland* (formerly known as VSNU), but also to legislation such as the GDPR.

In order to assist researchers in complying with (inter) university codes of conduct and legislation, all FSBS research that is human-related will be subject to review by the faculty's ethical review board (FERB).

Since 1 July 2019, it has been mandatory to notify the proposed conduct of scientific research to the FERB via the online registration system PRIDE before data collection starts.

From 1 September 2020, mandatory review also applies to all student research, including research that is not human-related, via the online registration system UU-SER.

Through FERB review, individual researchers will comply to the GDPR, the UU research data handling framework, in line with the Netherlands Code of Conduct for Scientific Integrity. More importantly, researchers:

- will be able to receive adequate support in drafting (GDPR-proof) communication to (potential) participants (consent and information letters);
- will be able to receive adequate support in drafting formal agreements when exchanging data (data processing agreements, data transfer agreements);
- receive formal ethical approval of their study.

## **Applicability**

The Faculty Ethics Review Board is tasked with providing a professional and independent review of individual research projects and series of related studies, also called research programmes, on ethical admissibility, integrity, data management and privacy aspects insofar as these are conducted under the faculty's responsibility.

Initially, the FERB assesses whether the research protocol could fall under the WMO (Medical Research Involving Human Subjects Act). If this is the case, the research has to be reported to a Medical Ethics Review Committee (METC) recognized by the WMO and the involvement of the Faculty Ethics Review Committee ceases. If the METC decides that the research project is indeed covered by the WMO, the research should also be insured. If the METC decides that the research project is not covered by the WMO, the Faculty Ethics Review Committee will test the proposal against a set of (ethical) criteria related to care, proportionality and decent treatment of participants.

## **Relationship FCI - FERB**

The FERB and FCI work closely together when drawing up new policies on integrity issues.

The FERB is one of the FCI's main policy instruments. The FERB has a central role in advising on and reviewing various integrity aspects, especially in the design and implementation phase. The dean sets policy on the advice of the FCI.

To work efficiently, two separate chambers may be set up for ethical review (including data management and GDPR, as is currently materialized in the Pride and UU-SER programs that support the review):

- a chamber for ethical review of staff research;
- a chamber for ethical review of student research.

The FCI monitors substantive coherence between review practices in the two chambers, identifies where quality and/or efficiency gains can be made, and provides a framework.

## **Composition of the FERB**

The composition of the FERB is such that it has sufficient spread of expertise to assess projects submitted for review. It is desirable to have someone with a legal background and a clinically competent researcher included in this committee.

### Appointment of FERB-members

The FERB has about 9 permanent members (about 3 members per department). Members are nominated by the department, taking into account the distribution mentioned above. The members are ultimately appointed by the board.

The board of the faculty appoints one of the members of the FERB as chair. It shall also appoint a deputy chair.

The chair may rotate between departments every 3 years. A 3-year reappointment may take place.

The secretary is appointed by the board.

The chair and members of the FERB are compensated in time for the work they perform. The amount of this compensation is determined by the board of the faculty.

## Term

FERB members are appointed for a 3-year term, after which reappointment for the same term is possible.

A member of the FERB shall not hold any ancillary positions that are incompatible with the proper performance of his duties and could harm his/her independence and confidence therein. To this end, he/she shall notify the chair of all ancillary positions that are incompatible with the proper performance of his duties as a member of the FERB.

Membership of the FERB ends:

- a. by voluntary resignation;
- b. by termination of the position with the faculty.
- c. after 2 terms of 3 years
- d. in the event of demonstrable dysfunction

Other than at own request, the faculty board may only dismiss members of the FERB in the interim on the reasoned nomination of at least two-thirds of the FERB members:

a. if they insufficiently fulfil the obligations arising from membership or chairship of the FERB;

b. if, on account of their physical or mental condition, they must be deemed to have lost the fitness to fulfil their duties.

The FERB secretary shall provide a record of the proceedings during the appointment and dismissal procedure.

## Daily management

The executive board of the FERB consists of the chair, secretary and privacy officers, including department head of data management. The executive board meets biweekly.

The executive board is in charge of:

- preparing matters submitted to the FERB and/or FCI for decision-making;
- sending the necessary documents to the members of the FERB;
- responsibility for implementing decisions;
- performing work that may result from further regulations;
- informing FERB members of relevant future policy matters.

#### **Guiding Principles Ethical Review according to the FERB**

• Do no harm:

Researchers are considered to avoid harm to the participants or minimize this.

Minimal risk:

Participants must not be exposed to more risk than they experience in their daily lives

Inform adequately:

Participants must be informed adequately about what they can expect by participating in the research project and how their data is being processed

• Apply or explain:

Researchers must apply to the principles of the national and international guidelines. If they cannot do so, they must explain why and what the alternative is.

Furthermore, the FERB follows the principles of The Code of Ethics which has been adopted by the ethics committees united in the National Ethics Council for Social and Behavioural Sciences<sup>1</sup>:

- ♣ Researchers respect the dignity of humans and their environment by avoiding exploitation, treating participants and their communities with respect and care, and protecting those with diminished autonomy.
- A Researchers strive towards a minimization of harm, and a just distribution of benefits and burden, with respect for the potentially conflicting interests of diverse (groups of) participants, communities, and society.
- A Researchers adopt an ethical attitude in which they are mindful of the meaning, implications and consequences of the research for anyone affected by it.
- A Researchers demonstrate the ethical attitude by i) active reflection on the ethical issues that may arise during, or as a consequence of, their research, ii) initiating a proper assessment of the potential drawbacks of the research for individuals, communities and society, and iii) monitoring for any developments that may impact upon ethical aspects of the research.
- A Researchers are able to account for, and communicate on their ethical reflection vis-à-vis different stakeholders, such as the participants and their communities, the own organization, scientific peers, students, funding agencies, and society.
- A Researchers conduct research that is scientifically valid, and that will plausibly lead to relevant insights in the field of the social and behavioural sciences.

The ways in which these principles are safeguarded may vary to some degree depending on the field of research. Moreover, raising ethical awareness of scientists requires them to be stimulated, by way of the questions and considerations put to them in the ethical review procedure. The Code of Ethics forms the basis of such review procedures, of which the detailed implementation may vary.

Principles according to the Netherlands Code of Conduct for Research Integrity<sup>2</sup>:

- Honesty
- Diligence
- Transparency
- Independence
- Responsibility

<sup>&</sup>lt;sup>1</sup> Gedragscode | Ethical code | Nethics

<sup>&</sup>lt;sup>2</sup> Netherlands Code of Conduct for Research Integrity | NWO

#### Ethical Review Procedure: decision making of applications by the FERB

Decision-making initially takes place via the online registration system PRIDE between the chair, a member of the department from which the application originates and a member of another department whereby these individuals, independently of each other. They provide feedback to the secretary about the submission (i.e. whether they approve the submission or not and, if not, what questions or request they have).

The aim is to reach a decision within 30 calendar days.

If the chairman establishes that no consensus can be reached between the persons mentioned in the first paragraph of this article, an attempt is made to reach consensus by email. Possibly one or two additional FERB members will be involved.

Then, if consensus still cannot be reached, the application is submitted to the entire committee by mail, unless it is desirable to convene in a physical meeting. At that, the committee can decide on the admissibility of the research protocol in question by a majority of the number of votes cast. Changes to the procedure are preferably made by unanimous votes, but in any case are only valid if at least two-thirds of the number of votes cast agree.

The chair may determine that, in exceptional cases, a written contribution from a missing committee member is also sufficient for decision-making.

If the chair or a member is in any way directly involved in a research protocol submitted for review, they will temporarily leave the meeting at the time this research protocol is being discussed.

Voting shall take place orally, unless the chair, whether or not at the request of one or more members present, decides to take a written vote.

The member expressing a minority opinion on a decision may request the secretary to explicitly mention this in the minutes.

The decisions of the committee with regard to cases where consensus has not been reached in the first instance, as outlined above, shall, if requested, be brought to the attention of the Faculty Board in writing with a copy to the lead investigator.

#### Meetings and reporting

The FERB meets once a month. If deemed appropriate by the chair, the FERB will give the project investigator and/or those under whose direction the project is being carried out the opportunity to explain the project at a committee meeting.

The secretaries of the committees plans the meetings and, in consultation with the chairman, determine the agenda. The secretarys then ensure that the members of the committee are sent the agenda and related documents one week before the meeting.

Meetings are private and confidential. The secretary shall keep minutes of the meetings. The minutes are approved at the next meeting, if necessary after making changes. Approved minutes are also confidential.

The FERB reports annually in September on its activities in the previous academic year. The secretary sends a copy of the annual report to the board.

## **External experts**

The FERB may seek advice from internal and external experts if this is required for proper and careful judgment. To this end, the experts may be invited to provide a written opinion and/or to join the committee meeting. Checks are made to ensure that the expert is not in any way involved in the investigation and/or has an interest or holds ancillary positions in the context of the investigation.

Where appropriate, experts in IT, GDPR, a representative of the faculty Open Science community, and qualitative research join the committee.

The committee is always aware of who the internal and external expert(s) are.

To the researcher, one-way blinding is used so that the researcher does not know who the external expert is.

The external experts are expected to treat the information they see about the case in question confidentially and not to share it with third parties.

The external experts only have access to those documents from the case file on which advice is to be given that are made available by the committee.

## Confidentiality

The chairman and members of the FERB are obliged to maintain the confidentiality of information that comes into the possession of the committee in the performance of its duties, the confidentiality of which is either explicitly indicated or implicitly apparent from the nature of the information.

The duty of confidentiality continues after termination of membership of the committee.

After termination of the membership of FERB, the members shall destroy the documents in their possession concerning the activities of the committee, or they shall hand over said documents to the secretary of the committee, who shall arrange for their destruction.

## **Complaints procedure**

In 2023 the FERB has changed her complaints procedure with a more independent part which entails that if necessary another ethical review committee within Nethics can give a second opinion. The steps of the renewed complaints procedure are as follows:

- The FERB gives its final judgment on the submitted research proposal.
- If the researcher disagrees with this judgement, he/she reports it to the FERB through the general complaint address (klachtenfunctionaris-FERBsocwet@uu.nl).
- The chair of the FERB enters into consultation with the researcher.
- If the disagreement persists, the researcher may report it/ file a complaint with the dean.
- The board of the faculty investigates whether the complaint is admissible. If the complaint is declared admissible, the board considers whether the review procedure was properly followed within a reasonable period of time. The board decides whether the complaint is justified and whether a second opinion by another ETC is necessary.
- If so, the dean submits the case via Nethics to a sister organisation, which gives an independent opinion based on all information (research proposal, opinion of FERB FSW UU, and any discussion and adjustments already made).
- The dean receives the judgment of the sister organisation and submits this judgement to the FERB of FSW UU, who can react to the dean.
- Based on all insights, the dean makes a final decision on the case.

## **Closing provisions**

The chairman, members and secretary may submit proposals for amendments of the regulations.

These regulations may be amended by a two-thirds majority vote of the members of the FERB, after which the amendment will be submitted to the board for approval.

In cases, not provided for in these regulations, the chairman and the secretary shall decide in consultation with the committee members of the FERB or the Faculty Board.

## Appendix: national and international guidelines for ethics and privacy

All applicable (inter-)national laws, regulations and guidelines on Ethics and Privacy. See also the document on the FERB website:

Ethics Review Board of the Faculty of Social & Behavioural Sciences | Relevant documents (uu.nl)

#### Also guiding:

## Medical/Psychological:

- Declaration of Helsinki of the World Medical Association (WMA)
- APA's Ethics Code
- Wet Medisch-wetenschappelijk onderzoek met mensen (WMO)
- CCMO-guidelines

## Discipline specific:

- Beroepscode van de Nederlandse Vereniging voor Pedagogen en Onderwijskundigen (NVO), 2021
- Gedragscode VoR voor onderwijsonderzoekers, 2009
- Code for Ethics for Psychologists, 2015
- Beroepscode voor Sociologen van de Nederlandse Vereniging van Sociologen (NVS), 2002
- Ethical Guidelines Antropologen Beroepsvereniging, 2019
- National Code of Ethics for Research in the Social and Behavioural Sciences involving human participants (Nethics), 2018
- EU Guidance note on Social Sciences, 2021

## Integrity and Privacy:

- Netherlands Code of Conduct for Research Integrity, 2018
- Guideline for the archiving of academic research for Faculties of Behavioural and Social Sciences in the Netherlands, 2022
- Faculty Protocol data storage, 2016
- GDPR (2018)
- Data Privacy Handbook RDM UU, 2023