

Regulations of the Faculty Ethical Review Committee of the Faculty of Social and Behavioural Sciences

The Faculty Ethical Review Committee (hereinafter referred to as the "committee") is an independent committee instituted by the Board of the Faculty of Social and Behavioural Sciences (hereinafter referred to as the "Board") as of 1 July 2014. The committee is to promote the faculty staff's awareness of moral standards and social responsibility in their actions as concerns the rights, safety and well-being of the participants in scientific research.

The committee has been allocated the task of arranging for a professional and independent review of individual research projects and a series of related studies as to their ethical permissibility insofar as these are conducted under the responsibility of the faculty.

Article 1: Institution and sphere of activity of the committee

The Board of the Faculty of Social and Behavioural Sciences instituted a Faculty Ethical Review Committee as of 1 July 2014. This committee operates for the purpose of issuing ethical advice concerning social scientific research on the basis of research protocols submitted to the committee by the researchers at the Faculty of Social and Behavioural Sciences (hereinafter referred to as the: "faculty").

The committee will, in the first instance, determine as to whether a research protocol is subject to the Medical Research (Human Subject) Act (WMO; *Wet Medisch Wetenschappelijk Onderzoek*; hereinafter referred to as the "Act"). If so, the study must be registered with a medical ethical review committee (MERC) acknowledged under the Act and the Faculty Ethical Review Committee will further refrain from involvement. If the MERC decides that the study is indeed subject to the Act, the study will have to be insured.³

If, on the other hand, the study is not subject to the Act, the FERC will review the proposal on the basis of a series of (ethical) criteria pertaining to due care, proportionality and the respectful conduct towards the participants.

Article 2: Definitions

In these regulations, the following terms and definitions are used:

- a **Board**
Board of the Faculty of Social and Behavioural Sciences
- b **committee**
the Faculty Ethics Review Committee as described in these regulations
- c **faculty**
the Faculty of Social and Behavioural Sciences of Utrecht University
- d **participants**
those, whether patients or otherwise, who voluntarily make themselves available for the purpose of scientific research
- e **project**
any intended scientific research, which should be detailed in a research description (protocol)

¹ These regulations are primarily based on the regulations of the Psychology Faculty Ethical Review Committee in Maastricht, which was the first university in the Netherlands to institute such a committee.

² Previously, the FSBS had an advisory committee who determined whether a scientific study submitted for review was subject to the Act and should, therefore, be submitted to a MERC.

³ In accordance with Article 7 of the Act, all research subject to this Act should be insured in order to cover any damages incurred by the subjects participating in the study. The faculty has taken out human test subject insurance with Van Lanschot Chabot, which is renewed annually as per 1 October.

- f* *researcher*
the person conducting the scientific study. If the work involved in the study is actually performed by a third party (other researcher, research assistant or any other assistant), the person delegating the work to this third party will be taken to be the researcher.
- g* *UU*
Utrecht University
- h* *scientific research*
social scientific research that may, or may not, be subject to the Act.
- i* *Act*
Medical Research (Human Subjects) Act

Article 3: Submitting a scientific study

Any study that is intended to be conducted should be submitted to the committee in accordance with the procedure as determined by the board for the submission of scientific research.

Article 4: Objectives and duties of the FERC

Paragraph 1: Within the boundaries of the sphere of activity as described in Article 1, the committee has the duty to perform professional and independent ethical reviews of scientific studies based on the research protocol presented.

Paragraph 2: The review of the scientific study is to safeguard the rights, safety and well-being of the participants in this study, such as:

- the protection of the participants' personal integrity;
- respecting the participants' rights and (ensuring) their realisation;
- observing the rules of proper conduct towards participants within the framework of scientific research.

Special attention will be paid to studies involving vulnerable subjects, such as minors and incapacitated persons.

In its review, the committee will take into consideration as to whether the burden on the participants outweighs the yields in terms of the knowledge acquired through the study.

Paragraph 3: The committee is authorised to review scientific studies involving the faculty's staff members. Furthermore, if and when an already submitted and approved study is proposed to undergo essential modification (in design, for instance), it is the committee's duty to review the alterations.

Article 5: Composition, appointment and membership of the committee

Paragraph 1: The committee's composition is such that it will have adequate distribution of expertise in order to assess the projects submitted for review. Preferably, a legal and a medical professional will have a seat in the committee.

Paragraph 2: The committee has 6 regular members (2 members per department). Their appointment by the dean will be based on the recommendation of their relevant department,

taking into account the aforementioned distribution of expertise. The members will ultimately be appointed by the board.

Paragraph 3: The appointment will be for a term of 3 years, after which reappointment for a similar period is allowed.

Paragraph 4: Committee membership ceases:

- a. when the relevant member voluntarily withdraws;
- b. the relevant member resigns from their position at the faculty.

Paragraph 5: Apart from being at their own request, the board may dismiss any member from the committee solely upon the motivated recommendation of at least two thirds of the committee members if:

- a. the relevant member does not adequately fulfil their responsibilities arising from their committee membership or presidency;
- b. the relevant member is deemed to be no longer adequately equipped for their position due to their physical or mental health.

Paragraph 6: The Secretary is responsible for reports on the course of events during the appointment and dismissal procedures.

Article 6: Chairmanship and Secretariat

Paragraph 1: The board appoints one of the committee members as the Chair. It will also designate a Vice-Chair.

Paragraph 2: Chairmanship will rotate every 3 years between the different departments.

Paragraph 2: The Secretary will be appointed by the board. The faculty will put adequate secretarial support at the disposal of the committee.

Article 7: External experts

Paragraph 1: The committee may seek advice from both internal and external experts if and when it deems it necessary for a proper and careful assessment. To this end, the experts may be invited to supply advice in writing and/or participate in the committee's deliberations.

Paragraph 2: The committee members will always be informed of the identity of the internal and external experts.

Paragraph 3: Communication with the relevant researcher will be single-blinded so that the researcher will be unaware of who the external expert is.

Paragraph 3: As regards the external experts invited by the committee, the provisions of Article 9 concerning secrecy and the specification and disclosure of ancillary jobs will apply accordingly.

Paragraph 4: If an expert is approached on an occasional basis, the Chair or Secretary will verify that the expert has no interest in the study concerned or holds any ancillary job that is of relevance in this specific context, and enters this in the records.

Paragraph 5: The external experts solely have insight into the documents in the file for which advice is sought, which will be made available by the committee.

Article 8: Decision-making

Paragraph 1: Decision-making will, in the first instance, take place by e-mail correspondence between the Chair, a member of the department from which the application originates and a member from another department, upon which these persons, independently from one another, inform the Secretary of their individual decision on the research protocol concerned.

Paragraph 2: The aim is to decide within 30 days.

Paragraph 3: If the Secretary observes that agreement between the persons referred to in paragraph 1 of this article cannot be reached, the case will be discussed in the next committee meeting.

Paragraph 4: If paragraph 3 applies, the committee will decide by a majority of casted votes on the admissibility of the relevant research protocol. Changes in the procedure will preferably be adopted unanimously, but are in any case valid solely if at least two thirds of the casted votes agree.

Paragraph 5: Decisions as referred to in paragraphs 3 and 4 can solely be taken in a meeting that is physically attended by the Chair, Secretary as well as three members, whom should each represent a different department.

Paragraph 6: In deviation from the preceding paragraph, the Chair may determine that, in exceptional cases, a written contribution by a missing committee member may also suffice.

Paragraph 7: If the Chair or a member is in any way involved in, or associated with, a research protocol submitted for review, they will temporarily leave the meeting at the moment the research protocol will be discussed.

Paragraph 8: Votes are cast orally, unless the Chair, whether or not at the request of one or more of the attending members, decides to vote in writing.

Paragraph 9: The member who holds a minority view as regards a decision, may request the Secretary to include this fact explicitly in their report.

Paragraph 10: The committee's decisions will be reported to the Board in writing, with a photocopy to be sent to the researcher responsible.

Article 9: Review and assessment framework of reference

All the applicable (inter)national legislation, regulations and guidelines as well as Codes of Conduct, Good Usage, and Good Clinical Practice will serve as a general review and assessment framework of reference for the committee. The following will also serve as a guide:

- Declaration of Helsinki by the World Medical Association (WMA)
- APA Ethics Code
- Medical Research (Human Subjects) Act
- Guidelines and codes of conduct of the CCMO Central Committee on Research Involving Human Subjects
- Professional code of the American Anthropological Association (2012)
- Professional code of the NVO Netherlands Association of Educationalists, Educational Theorists and Child and Youth Psychologists (2008)
- Code of conduct of the VOR Netherlands Educational Research Association (2009)
- Professional code for Psychologists of the NIP Netherlands Institute of Psychologists (2007) as well as other relevant NIP guidelines

- Professional code for Sociologists of the NVS Netherlands Society of Sociologists (2002)
- Personal Data Protection Act (*Wet Bescherming Persoonsgegevens; Wbp*)
- Code of conduct for the use of personal data in scientific research of the VSNU Association of Universities in the Netherlands (2005)
- Faculty protocol for data storage (2014)

Article 10: Secrecy and independence

Paragraph 1: The Chair and committee members are obliged to keep secret any information they come to have at their disposal in the exercise of their duties and of which its confidentiality is explicitly stated or implicitly follows from the nature of the information.

Paragraph 2: The obligation to observe secrecy continues to exist after the termination of committee membership.

Paragraph 3: The obligation to observe secrecy also applies to persons other than those referred to in paragraph 1 who are involved in the exercise of one or more committee duties.

Paragraph 4: After termination of committee membership, the relevant member will destroy all the documents in their possession that relate to the committee's work activities, or hand over such documents to the Secretary who will then arrange for their destruction.

Paragraph 5: A committee member will not fulfil any ancillary jobs that are incompatible with a proper fulfilment of their duties and their independence and might undermine the trust in their performance. To this end, they will notify the Chair of all their ancillary jobs that are incompatible with a proper fulfilment of their role as a committee member.

Paragraph 6: The Chair will keep a list of these ancillary jobs and will make this list available for inspection at the office of the committee's Secretary.

Article 11: Committee Board

Paragraph 1: The committee is managed by a Committee Board formed by its Chair and Secretary. The Committee Board will, in principle, convene whenever it deems it necessary.

Paragraph 2: The Committee Board is charged with:

- the preparation of affairs that will be presented to the meeting for decision-making purposes;
- sending the required papers to the committee members;
- the responsibility for the execution of decisions;
- performing the activities that are to be further determined in separate detailed regulations;
- informing the committee members about relevant policy issues.

Article 12: Meetings and minutes

Paragraph 1: The committee will meet on a monthly basis to discuss any cases on which no agreement could be reached in the manner as referred to in Article 8, paragraphs 1 and 3. On the initiative of the Committee Board, exceptions to the fixed meeting schedule may be made if necessary.

Paragraph 2: The Secretary will convene the meetings and, in consultation with the Chair, determine the agenda. The Secretary will subsequently ensure that the committee members will be sent the relevant protocols and the associated documents and other meeting documents one week prior to the meeting.

Paragraph 3: The meeting schedule is publicly available.

Paragraph 4: The meetings will have a closed nature. The Secretary will be responsible for the minutes of the meetings.

Paragraph 5: The minutes will be approved in the first, subsequent meeting, if necessary after any required corrections have been made. The approved minutes are confidential.

Paragraph 6: If this is deemed desirable, the committee may grant the researcher who submitted the project and/or the person(s) under whose leadership the project is to be executed the opportunity to provide the meeting with more details.

Paragraph 7: If necessary, the committee will consult with other scientific advisory committees at the faculty and/or university, such as the Scientific Integrity Committee.

Article 13: Remuneration

The Chair and member of the committee will be compensated for the work performed in hours based on a fixed rate and a rate per case. These rates will be determined by the Board.

Article 14: Documentation

Paragraph 1: The Secretary is responsible for a systematic storage of the committee's documents. A file will be composed for every application, in which all the documents and information pertaining to the application, assessment, etc. will be included.

Paragraph 2: Direct access to the documentation will be limited to the Chair and Secretary.

Paragraph 3: The secretary is responsible for the adequate safeguarding of the stored documentation.

Article 15: Annual report

Paragraph 1: The committee will report annually on its activities in the preceding calendar year.

Paragraph 2: The Secretary will send a copy of the annual report to the Board.

Article 16: Complaints procedure

The committee will further elaborate the provisions of Chapter 9 of the General Administrative Law Act (*Algemene Wet Bestuursrecht; Awb*) in order to provide for an internal complaints procedure. In the first instance, an objection may be lodged with the committee and in the second instance with the Board.

Article 17: Concluding provisions

Paragraph 1: These regulations may be amended by a two third majority of votes of the committee members, after which the amendment must be submitted to the Board for approval.

Paragraph 2: The Chair, Secretary as well as the members of the committee may make proposals for amendment.

Paragraph 3: In cases not provided for by these regulations, the Chair and Secretary will decide in consultation with the committee.

These regulations were determined by the Faculty Board without amendment on 5 June 2014.