Regulations
Faculty Ethics Assessment Committee
Humanities
(FEtC-H)
Utrecht University

8 September 2022

(with minor editorial changes 10 October 2022 and 15 June 2023)

Contents

1 Abbreviations and definitions 1
2 Objective and remit of the FEtC-H 3
3 Composition and appointment procedure 4
3.1 Chambers 4
3.2 Members 4
3.3 Chair 4
3.4 Secretary 5
3.5 Executive committee 5
3.6 Internal and external experts 5
4 Research to be assessed 6
4.1 Research with human participants 6
4.2 Data research involving human participants 6
4.3 Applications approved elsewhere 6
4.4 Research by students 6
4.5 Amendments 7
4.6 Research proposals (pre-assessment) 7
4.7 Post hoc advice 7
4.8 Medical scientific research 7
5 Assessment 9
5.1 Framework 9
5.2 Criteria 9
5.2.1 Adequate informed consent 9
5.2.2 Acceptable burden and risks for the participants 9
5.2.3 Adequate data management 10
6 Assessment procedure 11
6.1 Assessment period 11
6.2 Research: short route 11
6.3 Research: long route 11
6.4 Revisions 11
6.5 Amendments 11
6.6 Applications approved elsewhere 11
6.6.1 Within the EEA (EU plus Norway, Iceland and Liechtenstein) 11
6.6.2 Outside the EEA (EU plus Norway, Iceland and Liechtenstein) 12
6.7 Research proposals 12
7 Confidentiality and independence 13
7.1 Confidentiality 13
7.2 Independence 13
8 Meetings 14

9 Documentation 15
9.1 Applications 15
9.2 Correspondence 15
9.3 Minutes 15
9.4 Annual report 15
10 Complaints procedure 16
10.1 Applicants 16
10.2 Participants 16
Appendix A. Criteria for long-route research 17

1 Abbreviations and definitions

Term	Definition
application	description of the proposed research as submitted to the FEtC-H, including accompanying documents, such as the informed consent documents
consent	1. a legal basis for collecting and processing data of natural persons (in addition to other possible legal bases, see document *Ethics and GDPR*); and also: 2. an ethical requirement for participating in a research study. Both types of consent require the participant to have been adequately and fully informed about the research. The two types of consent can be combined in a single declaration of consent (see document *Guidelines on Informed Consent*)
data research	research using data originating from natural persons, already collected elsewhere, and where those persons are not approached (directly) by the researcher to provide data. Examples: corpora, social media
declaration of consent	declaration in which the researcher states that they have adequately informed the participant and in which the participant states that they have been adequately informed and consents, on the basis of the information provided, to participate in the research
EEA	European Economic Area: EU plus Norway, Iceland and Liechtenstein
EU	European Union
FEtC-H	Faculty Ethics Assessment Committee – Faculty of Humanities
H	Humanities
information letter	letter to (parent/guardian of) participant or to the management of an (educational) institution explaining the research
participant	a person who is subjected to procedures or required to carry out particular tasks by the researcher ('test subjects', 'respondents', 'participants', 'informants', 'observed persons', etc.)
research, didactic	research that is carried out within the regular educational curriculum
research, long route	research that does not meet the criteria for short-route research, see *Appendix A. Criteria for long-route research*
research, non-didactic	research that is carried out within an educational institution, but not as part of the regular educational curriculum

Term	Definition
research, short route	research that is designed in accordance with the common standards within the field of research, in which no vulnerable groups are involved, in which no special categories of personal data are collected and in which there is no deception, see *Appendix A. Criteria for long-route research*
vulnerable	with reduced physical and/or mental capacity or with an increased risk; this includes, for example, persons with relevant syndromes (e.g., aphasia, dyslexia, or autism), persons incapable of giving informed consent, minors, refugees, newcomers, detainees, homeless persons, people suffering from dementia, and persons from socially disadvantaged groups (e.g., from ethnic, cultural or sexual minorities)
UU	Utrecht University
WMO	Medical Research (Human Subjects) Act (*Wet medisch-wetenschappelijk onderzoek met mensen*)

2 Objective and remit of the FEtC-H

The Faculty Ethics Assessment Committee of the Faculty of Humanities (FEtC-H) is an independent committee established by the board of the Faculty of Humanities on 1 January 2019.

The FEtC-H's **objective** is to promote and facilitate ethically responsible conduct by the staff of the Faculty regarding the rights, safety and well-being of the participants in academic research. The FEtC-H safeguards rigorous and independent ethical assessment of academic research based on the research protocol presented, the applicable discipline-specific professional guidelines and the applicable laws and regulations.

The FEtC-H's **remit** is to provide independent assessment of individual research projects and series of related research projects as regards their ethical admissibility insofar as these are carried out under the direct or indirect responsibility of the Faculty of Humanities of UU (indirect in the case of external PhD candidates with a PhD supervisor at the Faculty of Humanities).

In its assessment, the FETC-H considers whether the knowledge potentially gained by the research outweighs the burden placed on and the risks for participants.

3 Composition and appointment procedure

3.1 Chambers

The FEtC-H consists of two chambers: (1) the Linguistic Chamber, which assesses research carried out at the Institute of Language Sciences, and (2) the General Chamber, which assesses other empirical research involving human participants within the Faculty of Humanities.

3.2 Members

The composition of the FEtC-H is such that its expertise is sufficiently diverse to assess projects submitted for assessment.

The General Chamber has 5 regular members (1 member per department of the Faculty of Humanities and one secretary). The Linguistic Chamber has 5 regular members (from various research groups within the UiL OTS and a secretary).

The FEtC-H has members who serve in an advisory capacity; these are the faculty data manager(s) and the faculty privacy officer(s).

Members are appointed by the dean at the chair's recommendation, following consultation with the research director(s) concerned, taking account of the distribution of members referred to above. Regular members (except the secretary) are appointed for a term of 3 years, following which they may be re-appointed for a further term of 3 years.

Membership of the FEtC-H ends:

a. by stepping down voluntarily;

b. by termination of the employment contract at the faculty;

c. upon completion of the term of the appointment.

Other than on their own request, the board can only dismiss the members of the FEtC-H before the end of their term at the substantiated recommendation of at least two-thirds of the members of that particular chamber:

a. if they do not adequately meet the obligations arising from serving as a member or as chair of the FEtC-H;

b. if they must be deemed to be no longer suited to serve in their position, due to their physical or mental condition.

3.3 Chair

At the recommendation of the members of the respective chamber, the faculty board appoints one of the members as chair.

The chairs of the chambers chair the meetings, represent the FEtC-H inside and outside the organisation (e.g., in network meetings), and are involved in or take the initiative to develop policies on topics regarding the FEtC-H.

The chair is appointed by the dean. The chair is appointed for a term of 3 years, following which the chair may be re-appointed for a further term of 3 years.

3.4 Secretary

The secretary is appointed for an indefinite period by the faculty board, and is also a member of both chambers.

The secretary assesses applications, monitors the assessment periods and communicates decisions to researchers. The secretary prepares the meetings, draws up the agenda in consultation with the chair and is responsible for meeting reports. The secretary draws up annual reports and is involved in network and other meetings and project groups that advance the quality of the FEtC-H's performance.

3.5 Executive committee

The executive committee of a chamber consists of the chair of that chamber and the secretary. The executive committee meets whenever necessary.

The executive committee is tasked with:

- preparing matters that are submitted to the meeting for decision-making;
- providing the necessary documents to the members of the chamber concerned;
- responsibility for the implementation of decisions;
- informing the members of the chamber concerned about relevant policy matters.

3.6 Internal and external experts

The FEtC-H may arrange to be advised by internal and external experts (from inside or outside the Faculty of Humanities, respectively) if that is required to arrive at a sound and rigorous assessment. To that end, experts may be invited to issue a written recommendation and/or to participate in the deliberations of the FEtC-H.

With regard to the external experts of the FEtC-H, the provisions set out in Chapter 7 ‘Confidentiality and independence’ concerning confidentiality and the notification and disclosure of ancillary positions, apply mutatis mutandis.

If an expert is involved on an incidental basis, the chair or the secretary ascertains that the expert does not have an interest in the research concerned, nor serves in ancillary positions that are relevant in that context.

The external experts only obtain access to the documents made available by the FEtC-H required to make a recommendation.

4 Research to be assessed

4.1 Research with human participants

The approval of the FEtC-H is required for any research in which data of participants are collected and which is carried out by researchers under the auspices of the Faculty of Humanities. Data collection can only begin after the FEtC-H has approved the application concerned, i.e.: after the researcher has received a formal letter of approval from the FEtC-H. See also paragraphs 6.2 *Research: short route* and 6.3 *Research: long route*.

4.2 Data research involving human participants

Faculty policy still needs to be formulated for research that uses *publicly* accessible data, such as radio or news broadcasts or messages on freely accessible social media pages and profiles. The FEtC-H can, however, be contacted for advice.

4.3 Applications approved elsewhere

Applications approved elsewhere concerning research that is also carried out at, or under the responsibility of, the Faculty of Humanities must be presented to the FEtC-H for assessment. To that end, an application must be submitted in the FEtC-H portal, with informed consent documents that are in conformity with sample documents made available by the FEtC-H on the website and on the intranet. See also paragraph 6.6 *Applications approved elsewhere*.

4.4 Research by students

Research that is carried out by students as part of their final paper or thesis or internship (BA and MA) is only presented to the FEtC-H in specific cases. Supervisors have final responsibility for the research that students carry out under their supervision. This applies to designing and carrying out research involving human participants by students, including the ethical considerations, the data management and the privacy aspects of the research carried out by the student. For more information, see the Guide for teachers/supervisors. Students are responsible for complying with agreements made with lecturers.

The specific cases are:

- research on which the student and/or supervisor wishes to publish in a peer-reviewed article in an academic journal or in a peer-reviewed (chapter of a) book;
- additional research conducted as part of an existing research project (of the lecturer) for which approval has been granted by the FEtC-H.

If, owing to education-related preconditions, it is not possible in these cases to present research to the FEtC-H *in advance*, the research must nonetheless be registered with the FEtC-H *as soon as possible*, and in any event *before commencing to write up the findings for academic publication*. In this regard, supervisors have a special responsibility to monitor very closely the ethical side of any research that has not yet been assessed by the FEtC-H. See also paragraph 4.7 *Post hoc advice*.

4.5 Amendments

Any amendment(s) of approved research that have an impact on the burden placed on or the risks for participants must be assessed again by the FEtC-H. For example, an amendment must be submitted if an application has been approved, but it becomes apparent before or after a pilot study that the research needs to be designed slightly differently and that this entails a change in the burden or risks.

These changes must be submitted to the chamber concerned as an amendment. See also paragraph 6.5 *Amendments*.

4.6 Research proposals (pre-assessment)

Research proposals written to apply for a grant (e.g., ERC) or research proposals that have already been approved (e.g., by NWO, the Dutch Research Council) may be assessed by the FEtC-H. Note: this assessment does not grant approval to the researcher to actually carry out the research. If the grant has been awarded, separate approval must be obtained for each (sub)study in the research proposal; see paragraph 4.1 *Research with human participants*. See also paragraph 6.7 *Research proposals*.

4.7 Post hoc advice

No formal approval can be provided for an application concerning research that has already started or has already been completed. The reason for this is that any required revisions (for example, of the informed consent documents) can no longer be implemented. In those cases, the FEtC-H issues an advice: if the research had been assessed in advance, the research would/would not have been approved.

4.8 Medical scientific research

Research that is subject to the WMO must be approved by a legally recognised Medical Ethics Review Committee (Medisch-Ethische Toetsingscommissie, METC), and not by the FEtC-H. Research is subject to the WMO if two criteria are met:

1. It concerns medical scientific research, and

2. Participants are subjected to procedures or are required to follow rules of behaviour.

Re 1: "Medical/scientific research is research which is carried out with the aim of finding answers to a question in the field of illness and health (etiology, pathogenesis, signs/symptoms, diagnosis, prevention, outcome or treatment of illness), by systematically collecting and analysing data. The research is carried out with the intention of contributing to medical knowledge which can also be applied to populations outside of the direct research population." (https://english.ccmo.nl/investigators/legal-framework-for-medical-scientific-research/your-research-is-it-subject-to-the-wmo-or-not). Research aimed at answering a non-medical research question is therefore not considered to be medical scientific research, and is accordingly not subject to the WMO.

Re 2: "In practice, research with human subjects is only subject to the WMO if there is an infringement of the physical and/or psychological integrity of the subject." (https://english.ccmo.nl/investigators/legal-framework-for-medical-scientific-research/your-research-is-it-subject-to-the-wmo-or-not).

Research that is subject to the WMO must be registered with and approved by the METC Utrecht (https://www.metcutrecht.nl/en/), and not by the FEtC-H.

5 Assessment

5.1 Framework

The FEtC-H assesses planned research regarding ethical aspects, within a framework consisting of all applicable international and Dutch laws and regulations, and ethical guidelines of the various subject areas. See the page concerned on the FEtC-H website.

5.2 Criteria

The FEtC-H assesses whether planned research meets the requirements for ethically responsible research, using three clusters of criteria:

1. Adequate informed consent: see paragraph 5.2.1 below.
2. Acceptable burden and risks for the participants: see paragraph 5.2.2 below.
3. Adequate data management: see paragraph 5.2.3 below.

5.2.1 Adequate informed consent

Participants must first be adequately informed about the research in which they will be participating, after which they must voluntarily be able to consent to participating in that research (*informed consent*). This consent is required from an ethical perspective, and in many research projects it also serves as the required legal basis for processing personal data (GDPR, Article 6.1.a). Researchers are bound by the detailed requirements for such consent in the Guidelines on informed consent.

No consent is required for didactic research (see the Guidelines referred to above) or for other types of research founded on a legal basis other than consent. Researchers are required to explain why informed consent is not used in their application, preferably following prior consultation with the privacy officer.

If consent forms the legal basis for the processing of research data, the legal description of consent applies for that purpose, and the researcher must be able to demonstrate that this consent was obtained in the appropriate manner (voluntary, specific, informed, prior, unequivocal, affirmative).

The FEtC-H provides researchers with guidelines for and examples of adequate provision of information (information letters) and consent (declarations of consent) for various situations. Both the actual information letters and the declarations of consent must be easy to understand for the target group.

The researcher must be able to demonstrate that the informed consent was actually obtained, and obtained in an adequate and correct manner.

5.2.2 Acceptable burden and risks for the participants

Do-no-harm is the guiding principle in research involving participants. The burden and risks for the test subjects must be acceptable, in reasonable proportion to the expected benefits yielded by the research, and in reasonable proportion to any (potential) remuneration. To that end the researcher must consider factors such as the burden in terms of the time to be spent, work to be performed, physical discomfort or hindrance (e.g. protracted sitting or standing or lying down), and of the risks of loss of privacy,

adverse long-term effects after the research (e.g., loss of self-confidence, loss of naivety when participating in future research).

If applicable, the burden and risks for third parties must also be taken into consideration; this may for example apply in the case of recorded conversations, in which the privacy of third parties (persons mentioned in the conversation between the researcher and the participant) may be violated.

Among the burden and risks for the participants, the researcher should also take into account potential *unexpected* (coincidental) findings: for example, research may reveal that a participant has committed a crime, or that a participant proves to have an undiscovered impairment (e.g., low reading proficiency). The researcher should also take these risks into consideration.

In some research projects, it is not possible to inform participants in advance about the objective of the research, as that information would have an undesirable impact on the participants' behaviour. In such cases, it may be necessary to refrain from informing participants fully or even to deceive them about the objective of the research. The participants must then be informed correctly retrospectively, after completion of the research in which they have participated, and must be given an opportunity to withdraw the consent they gave previously. Such *deception* forms an additional burden for the participants, and must as such be taken into consideration as well.

5.2.3 Adequate data management

Researchers must carefully keep, manage and archive the data collected, in accordance with the information that was provided to the participants and in accordance with the faculty policy concerning data management.

6 Assessment procedure

6.1 Assessment period

For all applications, in making a planning all researchers must take account of the assessment periods set out below and of possible re-assessment after any revision.

6.2 Research: short route

Research that is expected to meet the customary requirements of responsible humanities research will be assessed by two members of the chamber concerned. This expectation is based on an initial screening of the proposal in the FETC-H web portal. For such proposals, the aim is to send a decision to the applicant within two weeks. If these assessors have any doubts about the application, if the application is too complex or if no agreement is reached between the two members, the application will be discussed by the full chamber during the next meeting.

6.3 Research: long route

Research that is *not* considered to be short-route research in the initial screening in the FEtC-H web portal, or which has been found during the procedure not to be such research after all, is deemed to be long-route research by the FEtC-H (see *Appendix A. Criteria for long-route research* for an indication of the criteria applied for this purpose). This means that the application will be discussed by the full chamber during the next meeting. The meeting dates are published on the FEtC-H website. Applications must be submitted no later than one week before the meeting. The chamber concerned will decide by a majority of the votes cast whether the application concerned is admissible. Decisions can only be taken in a meeting that is attended by at least half the number of members, including the chair and/or the secretary. The chair may, however, decide that in exceptional cases a written contribution from an absent member will also suffice for the purposes of decision-making.

6.4 Revisions

Revisions are assessed by two members of the chamber concerned. If these concern minor corrections, the secretary's decision will suffice.

6.5 Amendments

See also paragraph 4.5 *Amendments*. Amendments are assessed by two members of the chamber concerned. The aim is to provide a decision on an amendment within one week.

6.6 Applications approved elsewhere

6.6.1 Within the EEA (EU plus Norway, Iceland and Liechtenstein)

Applications that have been approved by an ethics assessment committee of a research institute or university within the European Economic Area (EEA) will be treated as short-route research; see paragraph 6.2 *Research: short route*.

6.6.2 Outside the EEA (EU plus Norway, Iceland and Liechtenstein)

Applications that have been approved by an ethics assessment committee of a research institute or university outside the European Economic Area (EEA) will be treated as long-route research; see paragraph 6.3 *Research: long route*.

6.7 Research proposals

Research proposals are assessed by (at least) two members of the chamber concerned, with the aim of sending a decision to the applicant within 2 weeks.

7 Confidentiality and independence

7.1 Confidentiality

The FEtC-H maintains confidentiality in reporting to the (ultimately responsible) applicant.

The chair and the members of the FEtC-H are obliged to observe confidentiality with regard to data that come into the possession of the FEtC-H in carrying out its remit and the confidentiality of which is expressly stated or implicitly apparent from the nature of the data.

Members remain bound by the duty of confidentiality after termination of their membership of the FEtC-H.

The duty of confidentiality also applies to other persons who are involved in any of the tasks of the FEtC-H.

After they cease to be members of the FEtC-H, the members will destroy the (digital) documents in their possession that relate to the activities of the FEtC-H.

7.2 Independence

To avoid conflicts of interest, members of the FEtC-H who have any kind of involvement in a specific application will not participate in the decision-making process for that application. If the application needs to be discussed in a meeting, the member concerned will temporarily leave the meeting when the application is discussed.

Also, where relevant, the chairpersonship of the meeting will temporarily be transferred to a member not involved in the research proposal concerned. In the event that a chair has any involvement in an application, the chair of the other chamber will sign the formal letter of approval (ad interim).

Members of the FEtC-H do not serve in ancillary positions that are incompatible with the proper performance of their duties, and that may compromise their independence and the trust in their independence. To that end, they will inform the faculty board of all ancillary positions that are incompatible with proper performance as members of the FEtC-H.

8 Meetings

Each of the chambers meets every four weeks. The fixed schedule of meetings can be deviated from if necessary, on the initiative of the executive committee.

The secretary convenes the meetings and, in consultation with the chair, determines the agenda. The secretary then ensures that the agenda and the other meeting documents are sent to the members of the chamber concerned in a timely manner. See also paragraph 3.4 *Secretary*.

The schedule of meetings is public.

The meetings are confidential in nature. The secretary is responsible for reporting on the meetings. The minutes are approved in the next meeting, after implementing any necessary changes if required. The approved minutes are confidential.

The FEtC-H provides for ethical assessment by a minimum quorum of regular members: two members for short-route research (see also paragraph 6.2 *Research: short route*); at least half of the number of members, including the chair and/or the secretary, for long-route research (see also paragraph 6.3 *Research: long route*).
If the chamber deems it appropriate, the chamber concerned will give the researcher of the project and/or those under whose lead the project is carried out an opportunity to provide information on the project in a meeting of the chamber concerned.

If necessary, the FEtC-H will consult with the other academic advisory committees of other universities and/or the UU, such as the Research Integrity Committee.

9 Documentation

9.1 Applications

Applications and corresponding documents (including, for example, information letters and declarations of consent/objection forms) are submitted via the portal of the FEtC-H (https://fetc.hum.uu.nl/). The portal is the official storage location for applications. Approved applications are placed in a semi-public part of the portal, where they can be viewed by anyone with a Solis-id.

9.2 Correspondence

Correspondence regarding applications takes place via the mailbox of the FEtC-H, fetc-gw@uu.nl.

9.3 Minutes

The minutes of each meeting are stored on a secure server of the UU (O:\GW\Algemeen\FETC-GW).

9.4 Annual report

Both chambers jointly report annually to the faculty board on their activities during the preceding calendar year.

10 Complaints procedure

10.1 Applicants

In accordance with the provisions of the General Administrative Law Act (*Algemene Wet Bestuursrecht*, Awb chapter 9) concerning the handling of complaints, the FEtC-H provides for an internal complaints procedure. Objections can be filed, in the first instance, with the chamber concerned, and in the second instance, with the faculty board.

10.2 Participants

The information letter (which together with the declaration of consent or the objection form constitutes the informed consent documents) must state:

- that participants who wish to file a complaint concerning the procedure regarding the research can contact the secretary of the FEtC-H, email: fetc-gw@uu.nl;
- that participants who have a complaint or a question concerning the processing of personal data can contact the Data Protection Officer of Utrecht University (privacy@uu.nl) and that the latter can also assist them in exercising the rights they have pursuant to the GDPR;
- that participants have the right to file a complaint with the Dutch Data Protection Authority (Autoriteit Persoonsgegevens) (https://www.autoriteitpersoonsgegevens.nl/en).

Appendix A. Criteria for long-route research

As the FEtC-H aims to ensure that its assessment of research projects is as quick and efficient as possible, it differentiates between short- and long-route research (see paragraphs 6.2 *Research: short route* and 6.3 *Research: long route*). The FEtC-H web portal determines *automatically* on the basis of various criteria whether or not an application is likely to concern short-route research (in which case it will be short-routed towards accelerated assessment by two members).

The long route will be used to assess applications in the following cases:

a. there is a hierarchical relationship between the researcher(s) and participant(s);

b. participants belong to a potentially vulnerable group;

c. special categories of personal data are collected;

d. the researcher states that (or has doubts whether) the research might, in part or in its entirety, involve such a burden that it could give rise to questions about research ethics *despite the informed consent obtained*;

e. the *total* duration of the tasks in the session, excluding breaks and other non-task elements, *exceeds* the targeted maximum for the age group concerned (see table):

age group (years)	Maximum total duration of task (minutes)
0–3	20
4–5	40
6–11	60
12–17	90
18–69	120
70 and above	60

f. the researcher states that the risks of psychological, physical or other harm owing to participation in the research are (or that they have doubts whether those risks might be) *more than* minimal;

g. if the research uses deception.