Ethical review of empirical research with human subjects at the Faculty of Humanities from Utrecht University

REGULATIONS

All researchers involved in Faculty of Humanities research are expected to be aware of the content of these regulations (in their capacity as supervisors of student research as well as when carrying out research directly)

N.B. These regulations may be adjusted during the start-up phase of the FEtC-H assessment procedure; adjustments will be announced on the FEtC-H webpage.

Faculty Ethics Committee
FEtC-H
Humanities
Utrecht University

Faculty Ethics Assessment Committee - Humanities (FEtC-H)
Faculty of Humanities
Utrecht University
Version created April 18, 2019

1. Introduction

1.1 Why ethical assessment?

Ideas on quality control of empirical research into human behavior have changed substantially over the years. Researchers are increasingly expected not only to take into account the ethical acceptability of their research for themselves, but also to present it to an authorized committee for ethical assessment before proceeding. In some cases, formal ethical assessment of this kind is compulsory under new legal frameworks, but it is also increasingly a condition of subsidy providers and journal editors. Professional research organizations are also required to work with carefully drawn-up declarations of consent, and to treat the research data collected according to the declaration given in addition to relevant laws and regulations. The Faculty Ethics Assessment Committee for Humanities (hereafter FEtC-H) has been established to support Faculty of Humanities researchers in complying with these changed quality requirements, and at the same time to ensure that all the institute's research is carried out with comparable, adequate and ethically responsible procedures. The FEtC-H does this by checking every intended study with human participants beforehand according to criteria of informed consent, burden and risks to participants, and data-management procedures (with respect to confidentiality, archiving and reuse).

1.2 When to submit a study for an ethics assessment?

1.2.1 What kind of studies **should** apply for assessment?

- *Every* new study in which data on human behavior is collected from one or more participants ('human test subjects', 'respondents', 'informants', 'observees', etc.) and which researchers carry out in the framework of their Faculty of Humanities affiliation under the responsibility of the institute must be submitted to the FEtC-H *before* the research is carried out. This applies to studies in which the research participants are assigned special tasks ("Play with your child for 10 minutes as you would normally do", "complete this internet survey at home", "read these stories carefully", etc.), but also studies in which the participants during parts of their daily life are observed (for example on the street in certain neighborhoods, in school classes, during sports, or within organizations and institutional settings such as refugee centers, on digital public and private platforms, or at home with participants), as well as studies in which the participants are observed in their daily lives (for instance in schools or in other institutional settings, in a digital public space, or in the participant's home), whether or not something in the relevant setting is manipulated as part of the research (a different course of lessons, a different website, etc.). Human behavior should be broadly interpreted, ranging from spontaneous behavior in face-to-face interaction or on

social media, or behavioral, physiological and eye-movement reactions in laboratory settings.

- For guest researchers the following holds: If the study is already reviewed by the guest researcher's home institution, the study still needs to be registered at the FEtC-H. Ethical approval granted by the guest researcher's home institution does not in principle guarantee FEtC-H approval, but it may help accelerate the FEtC-H process.

- All research that is carried out at the UiL OTS lab, or with the help of the UiL OTS database of participants, must be submitted to the FEtC-H. This includes studies carried out by a guest researcher where (possibly at first) no member of the Faculty of Humanities is involved.

1.2.2 What kind of studies should not apply for assessment?

- Research not involving, or no longer involving, participants, such as the (re)analysis of existing corpora or other databases previously collected *for the purpose of scientific research* does *not* need to be presented to the FEtC-H. Such reuse of data, however, must conform to the declarations of consent given by participants at the time of collection.

- It is not possible to present a *series* of studies or a *type* of study (obtaining permission in one application for all video observation research for conversations about financial advice, for example, or for all short-term lexical decision research with adults). Researchers *can* apply to the FEtC-H for a preliminary assessment of research for a subsidy application (section 2.9.3).

- Studies that are conducted in the context of education (yet see for specific criteria the section (1.2.3) below).

1.2.3 What about research in an educational context?

For research carried out by students in the context of a Bachelor or Master of Arts or a Research Master's degree supervized by a researcher affiliated to the Faculty of Humanities in his or her role as a teacher, the specific situation determines whether this must be presented to the FEtC-H, and if so when. The following situations are distinguished:

DO submit for assessment

- Research that is supervised in the context of (R)MA education that is also part of a research project that is being carried out under the responsibility of the Faculty of Humanities under the supervision of a Faculty of Humanities researcher (read: about which will be published via the usual scientific channels, so not only in a thesis on Igitur but also in an article) must be submitted for assessment.
- Thesis research in the **Research Masters' in Linguistics** must *always* be presented to the FEtC-H.

Beware:

(1) where possible these studies should always be presented to the FEtC-H *in advance,*

(2) where education-related conditions make this impossible the study should be presented to the FEtC-H *as soon as possible*, and in any case *before beginning to write up for a scientific publication*. Supervisors have a special responsibility here to take particular care in monitoring the ethical aspects of student research that has not yet been assessed by the FEtC-H.

(3) Research supervised in the context of education that has been submitted in advance to the FEtC-H – and hence, can be assessed prior to the start of the study – is subject to a formal assessment. (See example (1), above.)
In cases where this is impossible (see (2), above), no formal assessment can be given: since the study has already been conducted, any necessary revisions (for example in the informed consent) can no longer be made. In such case, the FEtC-H only offers an **advice**: "If this study were assessed beforehand, it would have (not) met with approval".

DO NOT submit for assessment

- Research carried out *exclusively for pedagogical purposes* in the context of a BA, MA or Research Master's course (i.e. where Faculty of Humanities researchers are involved only for their course requirements) does *not* require presentation to the FEtC-H, **unless** (1) the research is carried out at the lab or with the help of the UiL OTS database of participants, see also section 1.2.1) or ((2) it concerns students of **RMA linguistics**: they must always submit their studies for testing in the context of their thesis.

Beware:

(1) This does not absolve the teachers involved of responsibility for the task of pointing out to students for pedagogical and other reasons (1) the importance of adequate informed consent, (2) the need for careful consideration of the burden and risks involved in the research, and (3) the importance of – and existence of legal guidelines for – confidential treatment of data. Teachers can make use of relevant parts of these FEtC-H regulations as well as the informed consent forms available through the FEtC-H website.

(2) For student projects for which the Faculty of Humanities supervisor can reasonably assume that the research falls under the WMO (Medical Research Involving Human Subjects Act, see section 1.3 and Appendix A) or might raise questions with the FEtC-H in relation to burden or risk to participants can *only* begin after (medical) ethical approval.

1.2.4 What about pilot studies?

The following points apply to pilot studies conducted with participants other than those who will be involved in the main study:

DO submit for assessment

- Pilot studies *in which the approach and results will be stated separately in the methodology section of an article about the main study* (generally concisely in a form such as, 'A separate sentence plausibility rating with 20 female participants who did not participate in the main experiment revealed that…') should be presented to the FEtC-H as a separate study via the regular application process. For example, this could relate to pilot testing of language material on the basis of which the final item set for the main study will be determined, or pilot studies with a questionnaire to determine the final subscales for the main study.

The FEtC-H is aware that researchers may see the studies discussed under (a) as irrelevant for separate assessment, but here again the importance of adequate informed consent, acceptable burden and risks, and adequate data handling applies. The fundamental principle of informed consent is at odds with the practice of 'quickly collecting some pilot data in the last fifteen minutes of a lecture' because there is a hierarchical relationship between students and teachers, and the option not to participate or to stop partway and leave the room is often insufficiently guaranteed (and in some rooms physically impossible). It is precisely this kind of research that is vulnerable to ethical weaknesses.

DO NOT submit for assessment

- Any other pilot studies do *not* require presentation to the FEtC-H. For example, a 'continuous pilot study' for an experiment in the intended final format (and as such covered by the FEtC-H application for the main study), or informal consultation with others in private circles or among colleagues to try out research or material.

1.3 Assessment by the FEtC-H or METC?

Faculty of Humanities research with a *medical* aim *and* in which the participant is provided with rules of behavior which are nontrivially burdensome or risky (see Appendix A for a definition of both criteria) falls under the *Wet Medisch-wetenschappelijk Onderzoek met mensen* (WMO, Medical Research Involving Human Subjects Act), and according to this act must always be submitted for assessment by a regional Medical Ethical Assessment Committee (METC). For Faculty of Humanities research involving collaboration with a hospital or healthcare institution and/or making use of equipment within that institution (such as an fMRI scanner at the University Medical Centre in Utrecht) in practice METC assessment may often also be required by the collaborative partners, even if no burdensome or risky rules of behavior are involved which would formally fall under the WMO. Once the study has been approved by the METC, it must *also* be presented to the FEtC-H, to comply with the institute's requirement for registration of studies, and because only then can the faculty's own ethics committee establish that the Faculty of Humanities can take responsibility for it. The FEtC-H assessment will tend not to differ from that of the METC in practice, and after approval by the METC the FEtC-H will generally be able to grant approval almost immediately.

For all Faculty of Humanities research involving human subjects which is *not* assessed by a METC (legally or in practice), internal assessment by the FEtC-H is sufficient.

1.4 What does the FEtC-H focus on in its assessment?

The FEtC-H assesses whether an intended study meets three clusters of criteria for ethically responsible research.

(1) *Adequate informed consent.* Voluntary participation is central to research with humans, and a good procedure for informed consent (i.e. an adequate information letter plus associated declaration of consent) should ensure that participants know what they are signing up to and what their rights are. Issues relating to acquisition, appropriate reward, observation in public spaces, and in cases of misrepresentation adequate debriefing, are relevant here (see section 3.).

(2) *Acceptable burden and negligible risk to the participant.* This is a question of the mental or physical burden on the participant due to the duration and nature of the study, and the risk of psychological, physical or other (e.g. economic, legal) damage during or after the study (see section 4.).

(3) *Adequate data management*. This relates to adequate archiving of data, careful compliance with agreements regarding reuse of that data, guaranteeing confidentiality of personal information, and registering research before starting out (see section 5.).

The FEtC-H does not consider it one of its regular tasks to comment on the scientific or social use of the research, nor the methodological validity of the studies offered – such issues are already ensured in other ways (such as careful recruitment of employees, selection of subsidy applications, scientific consultation, research visits, etc.), and will only be involved in the assessment in exceptional cases. The primary focus is on safeguarding the interests of the participants.

Starting points used here are relatively generic criteria for ethically responsible research, as established in the *Ethics Code* of the American Psychological Association,[1] European Union guidelines[2], *American Anthropological Association*[3] and, for medical research, in the *Declaration of Helsinki*,[4] and guidelines of the Central Committee on Research Involving Human Subjects[5] (See Appendix B for the full list of laws and regulations, codes of conduct and guidelines). Since more or less all of these guidelines must be interpreted in context, the FEtC-H also uses various subject-specific criteria relevant to research in language and communication, some of which are explicitly included in the application procedure, and some of which will arise in committee meetings. All this enables the FEtC-H to accomplish systematic *intersubjective collegial assessment*, i.e. a collective – and semi-publically documented – assessment by several colleagues operating independently and not involved in the research.

[1] http://www.apa.org/ethics/code.
[2] http://ec.europa.eu/research/participants/data/ref/fp7/89867/social-sciences-humanities_en.pdf
[3] https://www.americananthro.org
[4] http://www.wma.net/en/30publications/10policies/b3.
[5] See http://www.ccmo.nl.

2 How does FEtC-H assessment work in practice?

The FEtC-H consists of two chambers, the General Chamber (GK) and the Linguistic Chamber (LK, formerly known as ETCL). Researchers affiliated with the ICON, OFR or OGK research institutes are assessed by the AK. Researchers affiliated with the UiL OTS are assessed by the LK, see also section 2.7.

2.1 Submission via the web portal of the FEtC-H

Every new Faculty of Humanities study with human participants which does not fall under the exceptions discussed in section 1.2 must be submitted to the FEtC-H for assessment before work on the study is started. During the application, which is facilitated by a special FEtC-H web portal, the researcher fills in a list of questions providing all information necessary for assessment of the study, such as a summary of the research questions, source of financial support, nature of participants and method of recruitment, type of research (observational research, interventional research, task-based research), various specific details of the methodology, and the estimated burden and risks to the participant. The researcher should also send the FEtC-H the information letter and declaration of consent (based on the standard Faculty of Humanities formats for informed consent). In specific situations it is common to use verbal informed consent (see section 3.)

When registering a study with the FEtC-H, a good understanding of the following definitions is indispensable. Firstly, with respect to the *types* of research, the FEtC-H distinguishes between research in which humans are studied *during particular periods of their normal lives* ('observational research', 'interventional research'), and research in which they *are given extra tasks which they would otherwise not perform as part of the research* ('task-based research'). Precise definitions:

Interventional research. Research in which people *act as they normally would in similar settings in their everyday lives, but in which the researcher intervenes to manipulate something in the context* (e.g. a different textbook, a different treatment, or a differently designed website). The effects of that intervention can be observed at the time, but can also be established in retrospect, for example, through regular testing at the end of the academic year.
N.B. When participants have to perform an extra task during an intervention study (e.g. fill in a questionnaire), then this part of the study is considered to be a *task-based research* and must be entered in the portal in such a way.

Observational research. Research in which people *are observed in particular settings in their normal lives*, such as in schools or in other institutional settings, in a digital public space, or in the participant's home, *without the researcher intervening in any way*. The

behavior is visibly or invisibly registered through video/audio recordings, or logging of digital actions, but the products of that behavior may also be studied.

Task-based research and interviews. Research in which people *are assigned extra tasks for the study* (through particular instructions, such as 'fill in this internet survey', 'read these stories carefully', 'judge these sentences', 'keep a diary of your media use for 1 week;', 'do you want to describe your gender identity', 'take photos of places in your living environment that you find threatening and inspiring', 'find and share with us 10 photos from your private archive to be able to tell your life story', 'tell us about your holiday', 'play with your child for 10 minutes as you would at home', etc.). via certain task instructions, such as "fill in this internet survey", "read these stories carefully", "indicate to what extent the following statements apply to you", "keep a diary of your media use for 1 week", " do you want to describe your gender identity ","take photos of places in your living environment that you find threatening and inspiring","find and share with us 10 photos from your private archive to be able to tell your life story " "tell something about your vacation"," play 10 minutes with your child like you would at home ", etc.).People are thus asked to do something they would not do in their normal lives (or would not do in that way). Research at the UiL OTS lab is always task-based by definition, due to the location (even if the participants are only observed after their arrival). Research in which people are interviewed, participate in a focus group, or are asked to fill in a questionnaire at home or in the street, is also task-based research. In interventional research any extra tasks also count as task-based research.

Study. A study, the assessment unit for the FEtC-H, is defined as follows: research activities in which new data are collected from participants in one or more associated sessions. Generally, this unit coincides with a study for which researchers would write a methodology section in an article. A study may be purely observational, interventional, or task-based, or may consist of a mixture of these types.

Session. The entirety of the commitment which you require of a participant in one day. In task-based research in the lab, for example, that means everything which happens as part of the research from the moment you welcome the participant to the moment you part from them, including any necessary breaks. In task-based research involving an internet survey this means everything which happens as part of the research from the welcome screen to the conclusion of the (series of) survey(s), again including any necessary breaks. In interventional research, a 'session' can refer to a focus group, an interview or to a lesson in which a new method is used, and in observational research to a lesson in which the researcher merely records observations without intervening.

Task. This refers to a coherent sequence of actions which you instruct the participant to perform via a spoken or written set of instructions *exclusively for the study*, and which

would also be described as a 'task' in an article. If the specific task varies from item to item, with a single instruction covering all items (e.g., 'for a Dutch sentence judge the meaning, for an English sentence judge the grammar'), this should be treated as one task.

Research trajectory. The entire 'route' participants follow within a study. Often this will *in essence* be the same route for all participants, for instance first an observation phase, then an intervention phase, and then another observation phase, or a session with three different reaction time tasks plus a session with two questionnaires. Small differences between what is assigned to the different participants (e.g. in a between-subjects intervention design a lesson from a new textbook or from the regular one; or in a between-subjects task design a speed or accuracy instruction) can be treated as variants of the same trajectory. However, sometimes different participant groups will really follow different trajectories, for example involving a different number of sessions, more tasks or completely different tasks. Examples would be when older children are assigned more tasks than younger children, or an intervention study in which the pupils are studied but the teacher is also required to fill in a survey or is observed during the application of the intervention. In such cases every trajectory and the associated participant group must be specified separately. A trajectory can also include a co-creation process (for example the development of an exhibition, documentary, game or app) from consultation, development to reflection with a specific group and the involved stakeholders.

2.2 At what point should a study be registered?

Once a study has been specified in its final form to the level of detail necessary for ethical assessment, including adaptation of the informed consent forms for the study, the research can be digitally registered with the FEtC-H. If it turns out that certain required details are not yet known at the time of digital registration, the application can be saved in draft form to be completed later. An example application and a complete list of the portal questions is available on the FEtC-H website.

The FETC-H assesses studies based on the specifications submitted by the researcher. If it turns out later to be necessary to change the specifications, then the FEtC-H should be informed of this through an amendment (see section 2.9.1). Since reassessment may be necessary in such cases, the FEtC-H's judgement may be different from that given for the original study.

The final decision will be given by the FEtC-H in a period of a maximum of two, six or – in very exceptional cases – ten weeks, depending on the nature of the study (see section 2.5). When designing and planning his/her research the researcher should take into account the time needed for ethical assessment.

2.3 Who can register the study for assessment?

A study always needs to be registered by a **researcher with final responsibility**, a researcher holding a PhD and affiliated with the Faculty of Humanities who bears final responsibility for the study within the Faculty of Humanities, possibly due to their role as a teacher. PhD students, masters or undergraduate students, student assistants or other researchers who do not hold a PhD cannot act as researchers with final responsibility. If they possess a Solis ID, these other parties involved in the research, *can* set up the application in draft form, after which the researcher with final responsibility checks the draft application and, when after having approved it, formally submits it for assessment by the FEtC-H.

Faculty of Humanities researchers who also have other affiliations should register their research through the institution which bears primary responsibility for the research.

Research carried out by a *guest* researcher under partial responsibility of the Faculty of Humanities should be registered with the FEtC-H by a faculty staff member involved in the study, or, if *no* faculty staff member is involved, by the guest researcher him/herself. In the latter case the guest researcher should be in possession of a Solis ID (if necessary, a temporary application can be made by their host).

2.4 Where can the study be registered with the FEtC-H?

In order to make the procedure of submitting a study as streamlined as possible for the researchers and the committee, the FEtC-H works with a web portal, a special digital environment where the study can be registered. When a new study is registered through the FEtC-H portal, the researcher specifies all ethically relevant aspects of the planned study using a number of questions, and the information letter and associated declaration of consent are submitted to the FEtC-H as digital attachments. The FEtC-H also has a regular UU webpage containing other information in addition to a link to the web portal, including news about ethical assessment, the composition of the committee and its meeting schedule, the regulations and various models for informed consent.

2.5 How does the assessment procedure work and what is the time schedule?

Registrations are initially *screened* during submission through the FEtC-H portal and assigned to one of three categories which determine their subsequent treatment and duration of the process:

2.5.1 Research subject to the WMO (Medical Research Involving Human Subjects Act)

Research which on initial screening in the FEtC-H portal is seen to fall under the WMO (Medical Research Involving Human Subjects Act, see Appendix A) should first be approved for ethical assessment by a METC; only then can the application to the FEtC-H be completed.

2.5.2 Standard Faculty of Humanities research

Research which on initial screening in the FEtC-H portal turns out *not* to be subject to the WMO *and* on the basis of the description submitted seems very likely to fulfil the requirements for ethically responsible linguistic research within the Faculty of Humanities (see Appendix B for an indication of the criteria used for this) will be assessed by two members of the committee on an *accelerated* schedule, so that it will be decided within 2 weeks whether the study can begin. If doubts arise unexpectedly as to standard status, the registration must be discussed as non-standard Faculty of Humanities research by the entire committee at the next FEtC-H meeting.

2.5.3 Non-standard Faculty of Humanities research

Research not subject to the WMO which on initial screening in the FEtC-H web portal is assessed as non-standard Faculty of Humanities research, or which during the accelerated procedure for standard research is assessed not to fit the standard research criteria, will be treated by the FEtC-H as non-standard Faculty of Humanities research. This means that the study must be discussed by the entire committee at the next FEtC-H meeting. Researchers should take into account the fact that the result of the assessment in this case will take a maximum of 4 weeks. For all studies which at face value are not clearly standard Faculty of Humanities research (see Appendix B for help evaluating this) the researcher should take this period into account for his or her planning.

If the FEtC-H cannot reach consensus on the decision during the meeting based on the information available, additional information will be sought from the researcher or other (internal and/or external) parties. The study will then be discussed again at the *following* FEtC-H meeting, another four weeks later. See section 2.8 for a flowchart of the procedure.

Where the researcher needs to meet tight deadlines (in connection with short-term project funding, courses, visits by guest researchers, etc.) it is the responsibility of *the researcher* to submit the intended study in good time; the FEtC-H is not responsible for delays resulting from its assessment procedure and results.

2.6 What are the consequences of an FEtC-H decision?

The FEtC-H has established its assessment policy in consultation with the faculty management, and its decisions on the acceptability of studies are binding to researchers affiliated to the Faculty of Humanities.

Developments in society and experience in the field of research can lead to changes in the policy, and the acceptability of research may therefore always be a subject of discussion. The FEtC-H reserves the right to withdraw approval even for research which is already running (although this will of course only occur in very exceptional situations). In all cases the FEtC-H has the final word on the acceptability of Faculty of Humanities research. Only if the researcher with final responsibility believes that a rejection by the FEtC-H is due to *procedural mistakes* in the evaluation trajectory can a formal objection be submitted to the dean of the Faculty of Humanities.

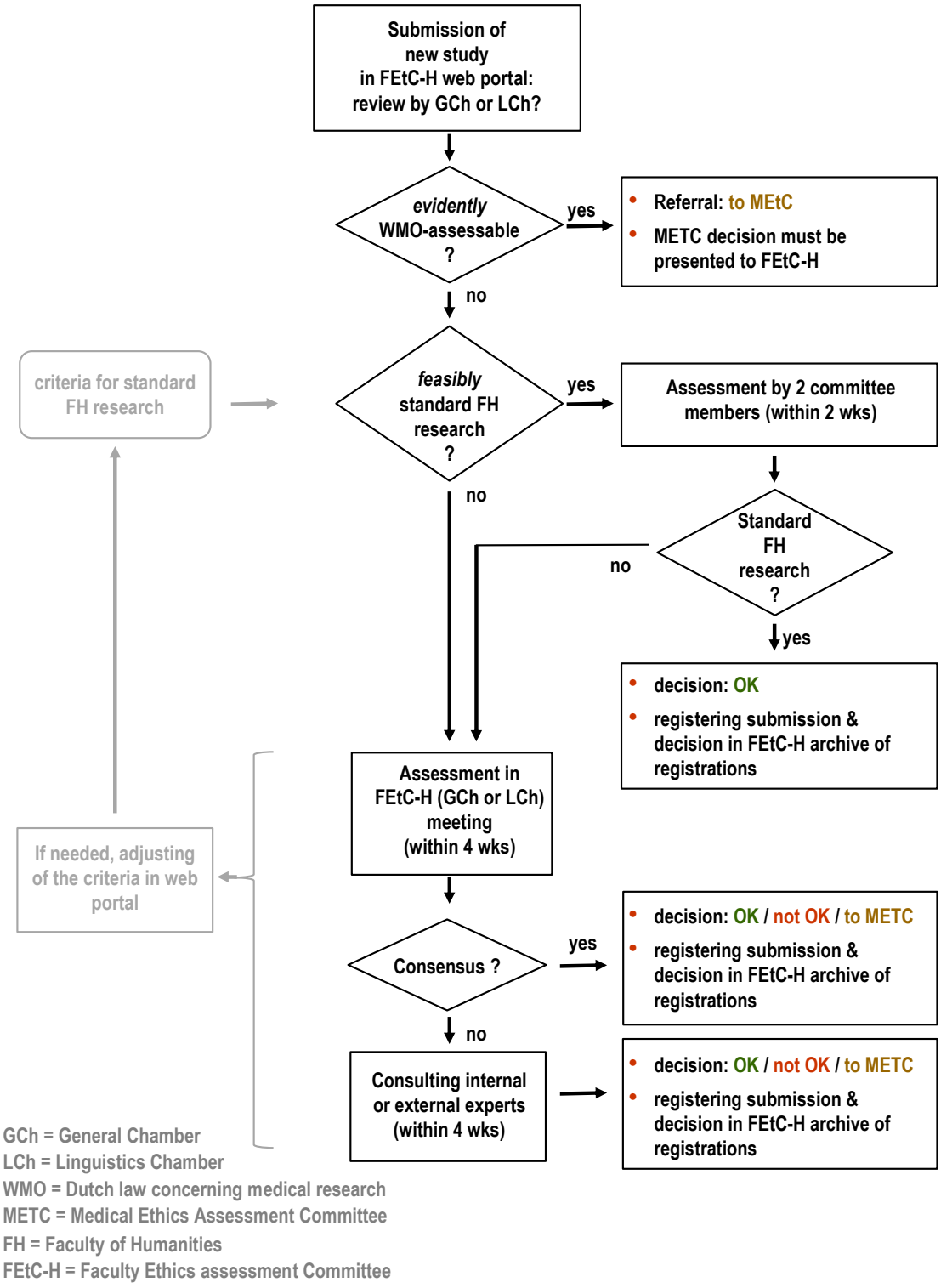
2.7 Who sits on the FEtC-H and when does the committee meet?

Both chambers (GC and LC) of the FEtC-H consist of five members, each appointed by the dean of the Faculty of Humanities for a period of three years. The aim is for the members of the committee to bring together sufficient expertise relating to the diverse kinds of ethical issues which may arise in Faculty of Humanities research. The current composition of the committee can be found on the website of the FEtC-H.

The FEtC-H meets on dates appointed in advance, and if necessary also on an ad hoc basis (for the meeting dates see here). During meetings all applications which have been submitted are discussed. The FEtC-H's policy is also adjusted where relevant (changes in procedure or adjustments to the definitions used will be easy to find at website of the FEtC-H).

The FEtC-H provides ethical assessment by a minimum quorum of *independent* Faculty of Humanities colleagues (two for standard research, at least four for non-standard research). Conflict of interest will be avoided by preventing committee members involved in a specific study from being involved in the decision on the study. Where relevant, chairmanship of the FEtC-H meeting will be temporarily transferred to a committee member not involved in the research discussed.

2.8 Flowchart of the regular FEtC-H assessment procedure



2.9 Special forms of assessment

2.9.1 Amendment in connection with changes to a previously approved study

When it emerges that a previously approved study requires adjustments *which would have led to a different specification in the original FEtC-H application* (e.g. different participant groups, a different intervention, more or fewer tasks, a different estimation of the burden or the risks), the researcher should inform the FEtC-H of this *immediately* via the portal; amendment of a study in progress. The FEtC-H will of course do its best to provide a prompt reassessment, but if the study has become much more ethically complicated due to the change, the decision can only take place at the following FEtC-H meeting. For questions as to the necessity of an amendment, applicants can contact the FEtC-H secretary.

2.9.2 Preliminary assessment of research for a subsidy application

The regular FEtC-H assessment procedure provides assessment of specific separate studies for which the resources are available and which can be specified in detail. Subsidy providers, however, increasingly also require ethical assessment (or other evidence of careful ethical evaluation) of *subsidy applications*. Since this relates to research which has only been worked out in outline with uncertain funding, a detailed application for regular FETC-H assessment is not yet relevant. In this case researchers can request a preliminary assessment from the FEtC-H, by uploading the relevant part of the application in a separate part of the FEtC-H portal; the preliminary assessment page. Since the assessment required is marginal and the funding application deadline is likely to be very close, in this case the FEtC-H will do its best to provide a decision promptly (within 1 week at most, with evaluation by two committee members). Subsidy applicants should take this period into account in their schedule, and for ethically complex research they should consider the possibility of a negative decision. The FEtC-H is not responsible for the consequences of the tight time schedule or of a negative decision in preliminary assessment. This marginal preliminary assessment does *not* replace regular FEtC-H study assessment; once studies have acquired funding and been worked out in detail they should still be submitted separately to the FEtC-H for thorough assessment.

The following three sections contain further information on the three pillars of FEtC-H assessment: adequate informed consent (section 3), acceptable burden and negligible risks to the participant (section 4), and adequate data management procedures (section 5). These are followed by a short conclusion and appendices.

3. Adequate informed consent

A crucial pillar of ethically responsible research with participants is adequately obtaining informed consent. The ethical guidelines with regard to informed consent of the various research traditions within GW, however, vary considerably. A distinction is made between written and oral forms of informed consent. The *quality* of informed consent is the most important criterion for the review committee.

3.1 Two forms of informed consent: written and oral

3.1.1 Written forms of informed consent.

Generally two associated documents are needed for this purpose:

a. The researcher uses an ***information letter*** in advance of the study to inform the intended participants (or in exceptional cases their representatives) of proceedings during and after the research so that they can properly judge what potential participation entails (including all potential advantages and disadvantages), and thus decide whether or not to take part voluntarily.

b. Using a ***declaration of consent*** (DC) presented with the information letter every participant then declares in writing that (s)he has been sufficiently informed and on that basis consent to participate in the research as well as to allow later use of the data collected (under the conditions specified in more detail on the form).

With the exception of the (special) cases discussed in section 3.2 and 3.3, for every study carried out under the responsibility of the Faculty of Humanities, the Faculty of Humanities researcher should use an adequate information letter and declaration of consent, *based on the relevant templates available on the FEtC-H website*, see information letter and declaration of consent, and customized to fit the specific study. Both documents must be comprehensible to the target group, even those members with a low level of literacy.
If the participant cannot read or write, equivalent verbal consent must be obtained in the presence of a witness, and such declarations should be recorded on video. This kind of research is always treated as non-standard by the FEtC-H.

The signed declarations of consent should be properly retained by the researcher with final responsibility for the study, and if this researcher leaves the Faculty of Humanities, they should be transferred to the secretary of the FEtC-H. In the case of declarations of consent recorded on video, data storage should be arranged in consultation with the FEtC-H secretary.

3.1.2 Oral forms of informed consent.

With regard to qualitative research, such as fieldwork and ethnographic research and research in highly politicized contexts, a signed consent statement may be not feasible and an adequate oral informed consent suffices. In the case of an oral informed consent, the researcher must clearly indicate how participants are informed and how permission is requested. In this type of research, the ethical section of the American Anthropological Association provides guidelines (see: https://www.americananthro.org/LearnAndTeach/Content.aspx?ItemNumber=22869).

Anthropological ethical guidelines emphasize the "co-production" of data / research material and state that signed consent statements can have a negative impact on the (trust) relationship between researcher and participants. Moreover, in this research tradition, informed consent is often seen as a continuous responsibility that applies throughout the entire process from data collection to publication (and therefore a one-time agreement is not sufficient). It is important that researchers are aware of the cultural, social and political context of consent agreement. The collection of informed consent (written or oral) is an important moment in the research process, but does not release the researcher from the responsibility to continue to deliberate during the research whether data collection and use of data are in line with what was agreed and / or whether there are unanticipated risks for the participants involved. Researchers who study societal issues and processes should be aware that in interviews, participants speak not only about themselves, but possibly also about others. This requires constant awareness of the ethical issues associated with data generation and processing.

3.2 Declarations of consent (DC) for different types of participants

One generic template is available for the information letter, but for the declaration of consent there are various templates which are more or less ready for use to fit the diverse types of participants commonly involved in Faculty of Humanities research:

- competent adults, 16+ years old (DC to be signed by the participant);
- adults, 16+ years old, incapable of giving informed consent (DC to be signed by representative);
- minors, 12 to 15 years old (DC to be signed by parent/guardian *and* child);
- minors, 0 to 11 years old (DC to be signed by parent/guardian);
- minors through a school, after-school childcare facility, day-care centre etc. (DC to be signed by management).

We use the following definitions and points of departure:

a. Competent adults are people from the age of 16 who can reasonably be assumed to be capable of judging what their potential participation entails (including all potential advantages and disadvantages), and who can consider their participation and come to an independent decision, without any question of a previously established hierarchical relationship with the researcher (i.e. the researcher is not his or her teacher, employer, etc.). These participants can give informed consent themselves.

b. Adults incapable of giving informed consent are adults who can reasonably be assumed to be insufficiently capable of judging what their potential participation would entail, and/or who for other reasons can be assumed not to be able to provide informed consent (e.g. because they cannot properly express their own opinion).[6] Here informed consent should always be obtained from a relevant representative.

c. Minors are children from 0 to 15 years of age. Here informed consent should always be obtained from parent(s) or guardian, either directly or indirectly, e.g. through the school or day-care center (passive consent, but see (d) and (e) below). In the case of children aged 12 to 15 in research involving direct informed consent, consent is also asked of the children themselves.

d. In the following situations an active consent is always required: In case of video recording; When participants are taken out of the classroom by the researcher or experimenter; When the research targets a vulnerable group of participants (e.g. people with a disability and/or people unable to understand the passive consent in the language of the application); When sensitive information is collected as part of the study (e.g. educational level of the parents, family situation, alcohol and drug use…). When the teacher is the investigator.

e. In all other situations, **active consent is preferred** but may be waived provided appropriate argumentation.

The above-mentioned informed consent templates can be found on the FETC-H website here: information letter and declaration of consent, where there are also some completed examples.

[6] http://www.ccmo.nl/nl/wilsonbekwame-volwassenen

3.3 Informed consent procedures in special cases

This section clarifies the informed consent procedure to be followed in a number of special Faculty of Humanities research situations.

3.3.1 Research involving tasks by internet or post

In research where the participant is asked to carry out a task (experimental task, questionnaire, etc.) *without the researcher and participant meeting in person* (e.g. a survey or experiment carried out through a website, or a questionnaire sent out by post and filled in at home) the researcher should *still* use the regular Faculty of Humanities information letter and declaration of consent. In a web survey or web experiment the relevant forms can also be integrated into the web environment, via webpages shown before the actual research; here the required signature can be replaced by a box to be ticked.

Only if the study is carried out *completely anonymously* (i.e. the researcher cannot trace the data back to specific people) *and* is not expected to be burdensome or risky at all, can the procedure for informed consent be appropriately shortened, for instance by informing the participant that he or she is implicitly giving consent for use of the data by filling in the questionnaire. Of course, it is important even in completely anonymous web surveys or web experiments to adequately inform the participant in advance (e.g. by giving correct information about the expected duration).

3.3.2 Observational research

The following applies to observational research:

a. If the research makes use of *publicly* available information, such as radio or news broadcasts or reports on social media, no informed consent is needed, and only the regular privacy and copyright laws apply.

b. If the observations are *not* carried out in a public space but in a private environment, as in the case of conversations about mortgages or police interrogations, informed consent must be obtained. In cases where obtaining informed consent *in advance* would threaten the validity of the observations, the informed consent should be obtained in retrospect, as soon as possible, and at the latest when completing the entire data collection phase.

c. In observational studies in which the researcher acts under cover in a non-public space with an administrator (e.g. a face-to-face or digital discussion group requiring registration), the researcher should obtain informed consent from the administrator. If the data is passively collected and *cannot* be traced back to individuals, it is sufficient to obtain consent form the administrator. In all other cases (when the researcher takes

part actively in the discussion and/or the data can be traced back to individuals) the FEtC-H will consider the matter at a meeting.

3.3.3 Course research

For research carried out among *students during a course* without a pedagogical aim (e.g. a pilot test of material in a lecture room), special attention should be given to correctly obtaining informed consent, given the hierarchical relationship between students and teacher. The researcher should make it clear to students what they can expect, that participation is voluntary, that they can stop at any time, and that they can decide to withdraw the data afterwards (see section 4.2). Participation on this kind of non-pedagogical research during a course can never count as assessment of the student.

3.3.4 Research with minors

In research with minors the following applies with respect to a number of special cases:

a. If the research takes place in a host institution where the child is not interned (e.g. a school, after-school childcare facility, day-care center), and if an active informed consent procedure can reasonably be expected to provide insufficient positive response, in some cases researchers can work with a passive informed consent procedure (see section 3.1 *d* and *e* above), whereby the management of the institute concerned gives consent and cooperates in the procedure through timely (i.e. at least 2 weeks before starting research) and adequate dissemination of information about the study; the parent(s) or guardian can then let the management know verbally or in writing if they do *not* consent to participation. Effective dissemination of information entails handing over or sending the information letter drawn up by the researcher to the parent or guardian of every child *individually*. In this type of passive consent procedure, the management should also sign a declaration of consent themselves.

b. If the research takes place in a host institution in which children are interned, and the management of that institution is authorized to decide as to participation in the research without consulting parent(s) or guardian (a point which must be demonstrated to the FEtC-H), a declaration of consent is filled in and signed by or on behalf of the management of the institute.

3.3 Misrepresentation and debriefing

Misrepresentation (intentionally providing inaccurate information as to the aim and/or important aspects of procedures during a study) is at odds with the principle of informed consent, and should therefore be avoided wherever possible. Often that is easy: the description of a study can normally avoid being so specific as to give the participant crucial information which would threaten its validity, while still being precise enough to give the

participant a sufficiently concrete idea of what to expect and an outline of the purpose. Sometimes, however, such a compromise is not possible and the study can only be valid when misrepresentation is used. This might involve an intentionally misleading cover story for the study, falsely suggesting that other participants are cooperating, offering a crucial memory task without warning, or giving false feedback.

As far as the FEtC-H is concerned, ethically relevant misrepresentation only comes into question if the inaccurate information could interfere with the informed consent procedure and/or lead to an unpleasant surprise or other negative attitude on debriefing. The widespread use of fillers in studies, stimuli which conceal the researcher's specific goal and for which the data is not used, is not seen by the FEtC-H as being an ethically relevant form of misrepresentation.

The FEtC-H only permits misrepresentation if *all* of the following conditions are met:

a. There is no practically achievable possibility of answering the question *without* misrepresentation.

b. Participants are *not* misled in a way that could reasonably lead to their *underestimating* the expected burden and/or potential risks involved in participating in the study.

c. Participants are *debriefed* as soon as possible after the study, i.e. adequately informed about the way they were misled and the reasons for it. If negative effects can reasonably be expected of the misrepresentation (e.g. if incorrect negative feedback is given on scores), then this debriefing must take place immediately after the end of the study, in such a way that it can reasonably be expected that the negative effects on e.g. self-image and mood will be directly removed by the debriefing. If such negative effects are not expected the debriefing can also take place at a later time, but before completion of the entire data collection phase.

d. The participant is explicitly told at the end of the debriefing that he or she can still withdraw from participation in the study if he or she wishes. Such withdrawal is *always* a participant's right (see section 4.2), but in cases of misrepresentation the researcher must always explicitly mention it again.

Depending on the specific nature of the misrepresentation the FEtC-H reserves the right to reject cases which fulfil these four conditions, giving an explanation of the reason for rejection.

If no misrepresentation has taken place in the sense described above, the FEtC-H assumes that the information letter for informed consent contains sufficient information about the

study, and that further debriefing is therefore unnecessary. Of course the researchers are free to provide further information in the interests of the participants and the study.

3.4 Recruitment and compensation

In recruiting participants it is *not* necessary to mention all information about the study required for informed consent at that moment. It *is* important when recruiting to mention anything which could be expected to put off a non-negligible number of potential recruits from participating. Examples might include significant physical or mental burden associated with tasks, strong emotional stimuli (e.g. material offensive to the average participant or to people with a particular character or religious conviction), or other matters which are non-trivially burdensome or risky.

Informed consent relies on voluntary participation. This means pressure cannot be placed on people to participate in any manner whatsoever (including peer pressure), regardless of whether they are approached as an individual or as a group. Participants should also not be presented with the prospect of a disproportionate reward For the type of research where reimbursements are common (such as gift cards, booklets for children or money pro rata), the Faculty of Humanities applies maximum reimbursement rates for participation in various types of research, for example see the UiL OTS labs site.

4. Acceptable burden and negligible risks

A second ingredient of ethically responsible research with participants at the Faculty of Humanities is that the research does not unacceptably burden participants, nor expose them to non-negligible risks which might lead to damage after the study. During the registration of the study the researcher is requested firstly to give an informed estimate of this him- or herself by responding to two crucial questions with the most vulnerable participant group in his or her study in mind:

Burden during the study: Are parts of the study or is the study in its entirety so burdensome to participants that it could raise questions (or even lead to outrage), e.g. among the researcher's colleagues, the participants themselves, or parents or other representatives, *despite informed consent having been obtained*? This could be the case, for example, in an 'inhumanely' long and exhausting task, a very confrontational questionnaire, or constant destructive feedback, or in cases of perceived intrusion on privacy, or other perceived lack of respect.

Risks of later psychological, physical or other damage as a result of the research: Are the risks of later psychological, physical or other damage (e.g. social, economic, legal) as a result

of participation in the study *more* than minimal? I.e. is the chance of and/or magnitude of possible damage to participants clearly *greater* than 'background risk'? When considering damage, researchers should take into account the possible consequences to the participant or others of certain information becoming available, for instance relating to self-image, stigmatization by others (parents, teachers, etc.), economic damage due to linking of data, etc. The background risk is that which healthy average citizens in the relevant age category normally encounter in their daily lives. The background risk of psychological and physical damage also encompasses e.g. the risks of 'routine' tests, studies or procedures which take place in everyday pedagogical, psychological or medical contexts (such as a final academic exam, a driving test, a stress resistance assessment, an intelligence or personality test, or a heartrate measurement after physical exertion; all under the supervision of adequately trained specialists where relevant). The background risk of other damage also encompasses e.g. the normal risks of stigmatization by teachers on the basis of tests. The essence of this question is that participating in a Faculty of Humanities study must not make life 'more dangerous' or 'more risky' than is normally the case.

N.B. 'Burden' here refers to the perception *during* the study, while 'risk' refers to *later adverse consequences* of the study (a later negative self-image caused by the study, although it is certainly 'burdensome' to the participant, should therefore be termed a risk in the FEtC-H application).

Due to the lack of hard criteria (such as damage statistics) and the researcher's potential subject-specific bias it is particularly important when estimating burden and risks that the FEtC-H makes a judgement (intersubjective peer assessment) in the first screening, with committee consultation if necessary.

4.1 Potential vulnerability of participants

In order to properly estimate the burden and risks of task-based research or interventional research it is necessary for the researcher when registering the study to supply information about how long a session lasts and what sort of tasks or interventions will be used, as well as stating whether the intended participant groups are more vulnerable than average. Less can be asked of a preschool child, for example, than an 18-year-old student, and participants of a study of the impact of verbal bullying, intentionally selected because they were bullied a great deal themselves in the past, are probably at higher risk than participants without such a history. Coincidental interactions between characteristics of the participant which are not known to the researcher and the type of study of course cannot be excluded, and candidate participants can also take their own responsibility for this through adequate informed consent ('I was so often bullied in the past, I don't think I will take part in this study.'). The FEtC-H will, however, pay close attention to foreseeable

interactions between the nature of the study and special test groups (children, patients, etc.).

4.2 Withdrawal during or after the study

Every competent participant in Faculty of Humanities research is free to leave the study at any moment for any reason without suffering adverse effects. Compensation earned up until that point is paid pro rata. No pressure to continue participating (including peer pressure) can be placed on people approached individually or as a group, nor can a higher level of compensation be offered than was agreed before the study.

Of course adults who are unable to give informed consent and minors also have the right to stop participation at any moment, on their own initiative or that of their representative. In these cases, however, the researcher should be particularly careful that the research is not overly burdensome. The moment researchers notice that a participant unable to give informed consent feels in any way uncomfortable or is really showing signs of resistance, the research should be stopped immediately. See the relevant webpages of the Central Committee on Research Involving Human Subjects on this point.[7,8]

Once the Faculty of Humanities study is complete the participant (or their representative in the case of those unable to give informed consent and minors) can still decide that the data collected cannot be used, and can do so without giving reasons. The researcher with final responsibility for the study or the researcher carrying out the study should be informed of such a decision either verbally or in writing within 5 days (or longer if that is explicitly agreed in the declaration of consent) after completion of the study, or, in the case of misrepresentation, within 5 days after the debriefing. The data of participants who have withdrawn during or after the study should be destroyed immediately, or, if that is impossible due to digital archiving, marked as unavailable for analysis.

This section applies to all research for which informed consent is required. In interventional and observational research where separate rules apply to the primary activity (e.g. the participants are at school and cannot opt out of this) the rules regarding withdrawal of course apply only to the research component.

4.3 Safety and hygiene

Research at the UiL OTS laboratory or other specially assigned testing rooms should take place in a safe and hygienic experimental environment, and the researcher carrying out the

[7] http://www.ccmo.nl/nl/wilsonbekwame-volwassenen
[8] http://www.ccmo.nl/nl/onderzoek-bij-minderjarigen

study should have had an adequate introduction to the use of equipment. See uilots-labs.wp.hum.uu.nl for full information about the UiL OTS lab facilities. For psychophysiological research this requires extra attention due to the nature of observation (generally through electrodes on the skin) and the complexity of the equipment; the researcher should make sure he or she is well informed about this by the UiL OTS lab support team.

4.4 Chance findings

In research it sometimes happens that something is seen in the data collected from a participant which the researcher was not looking for, but which for medical or other reasons *could be* important for the participant to know. For example in psychophysiological research that might be an abnormal heart rhythm or EEG, or an abnormality in an MRI scan. In Faculty of Humanities research with such measuring methods in practice this could only occur in those situations in which research techniques are used in a medical context (e.g. the MRI scanner at the UMC), since collaborating experts there contribute clinical knowledge when examining the data; such cases are already covered in the METC assessment which is compulsory for such research and by the associated informed consent procedures.

A category of chance findings which might occur in Faculty of Humanities research and which does not come under the METC is standardized test scores in language development research. Where such tests are properly standardized and there is also a clear issue of abnormal scores which are at odds with the good development of the child, the researcher should inform the parent(s) or guardian of this – if necessary after consulting colleagues. In such research this possibility should always be mentioned in the information letter, so that any ad hoc provision of information is covered by the consent given. It is also important that such information is provided *with care*, always referring to competent authorities for further investigation. Think of phrases such as 'We noticed that your child's score in this test was below average compared with other children his age. In order to gain a better view of your child's language development, if you wish we can repeat the test in half a year's time.' In such cases it should always be made clear that *clinical or orthopedogogical* interpretation falls outside the expertise of the Faculty of Humanities.

4.5 Insurance

For all Faculty of Humanities research, in the case of material or personal damage to third parties (such as participants and those accompanying them), the institute can call on the UU-wide liability insurance (AVB). For research subject to the WMO (Medical Research Involving Human Subjects Act) special participant insurance should be arranged for each study. For this purpose Faculty of Humanities researchers can join the insurance policy

which the Faculty of Social and Behavioral Sciences along with the Faculties of Science and Veterinary Medicine have arranged in the name of Utrecht University as a legal entity. For further information readers can contact the secretary of the Faculty Ethical Assessment Committee (FETC) of FSW, fetc-fsw@uu.nl (see also https://intranet.uu.nl/facultaire-ethische-toetsingscommissie-fetc).

5. Adequate data management

A very important third ingredient of ethically responsible research involving participants at the Faculty of Humanities is that the research data and personal data collected are handled properly. As a general principle, researchers should behave appropriately in storing data and making it available for other researchers and should observe the applicable laws.

[This will soon be worked out in detail, in part depending on the crystallisation of the UU data management policy and associated Faculty of Humanities policy. Until then we refer to the relevant frameworks.]

5.1 Anonymity, confidentiality, reuse

For the moment see the VSNU code of conduct and the Data Protection Act.

5.2 Archiving

For the moment see the VSNU code of conduct and the Data Protection Act.

6. Conclusion

Ethically responsible research is a responsibility shared by everyone involved. The FETC-H provides a systematic procedure by which Faculty of Humanities researchers receive help and a second pair of eyes from colleagues in assessing the ethics of their intended studies. These colleagues may spot issues which the researcher him- or herself has underestimated, or which simply escaped his or her attention. This assessment, however, inevitably takes place on the basis of the description submitted by the researcher with final responsibility. Formally organized ethical assessment therefore also remains a matter of trust, with the final responsibility remaining where it should be.

Feedback? The FETC-H has set up the procedure described above and the associated web portal with care, but the personnel *resources* for extensive *usability assessment* in the current context are relatively limited. Suggestions for improvement are therefore always welcome! Please send them to the committee secretary at fetc-gw@uu.nl

Acknowledgements and colophon In setting up the assessment procedure the FETC-H has received valuable advice from: Myriam Nijssen (UU Legal Affairs), Charlotte Onland (UMCU), Margret van Beuningen (RUN), and students of the Master's in Applied Ethics (Andrew Baumgartner, Rosalie Pronk and Roel Wouters). We were also inspired by the procedures of other assessment committees in the country, including those of the Psychology Departments at the UvA, Leiden University, the CLS and the Donders Institute in Nijmegen, ASCOR in Amsterdam, and the Faculty of Social and Behavioral Sciences at the UU.

The FEtC-H procedure was designed by Frank Wijnen, René Kager, Ellen Gerrits, Tessa van Charldorp, Maartje de Klerk and Jos van Berkum. The regulations were drawn up by Jos van Berkum and Maartje de Klerk. The web portal and associated website were set up by Ty Mees and Maartje de Klerk. Thanks to the researchers who helped with the usability tests for this portal.

Appendix A. When should a study be tested by a METC?

Research at the Faculty of Humanities is rarely 'medical' in nature. Nevertheless researchers should check whether any study is subject to the WMO (Medical Research Involving Human Subjects Act). In that case the FEtC-H is not authorized to approve the study independently. Instead the study should first be submitted to a recognized METC (e.g. that of the UMC Utrecht or of another institution involved in the research).

By law[9] research formally falls under the WMO if *both* of the following criteria apply:
(1) Medical research is involved; *and*
(2) People are subjected to treatments or assigned rules of behavior.

A.1 When is my study of a medical nature?

Medical research is defined by the WMO as *'… research which aims to answer a question in the area of disease and health (etiology, pathogenesis, symptoms, diagnosis, prevention, outcome or treatment of disease) …* [and which] *… aims to contribute to medical knowledge.'* If a Faculty of Humanities study does not have the aims described above it is *not* subject to the WMO.

Faculty of Humanities studies in which participants with diagnosed speech or language disorders (such as aphasia, SLI, dyslexia, dysarthria or verbal apraxia) are studied may be medical in nature (in the sense of the WMO), but only if the research aims to contribute to *medical* knowledge, *or* if one of the practical criteria below applies.

A practical test to work out whether your study is medical in nature – or would be seen as such by others – is to consider whether a *hospital or healthcare institution* is involved in the research, as when:

- one or more employees of a hospital or healthcare institution are involved in the study as a client or provider/executor, or
- the research takes place on the premises of a hospital or healthcare institution, and due to the nature of the research it would not normally take place elsewhere, or
- patients/clients of the institution (in their capacity as recipients of treatment) take part in the research.

If *no part* of your study is medical in nature then assessment by the FEtC-H is sufficient. If your *is* medical, even in part, then section A.2 is relevant.

[9] WMO art. 1, part 1 under b. See http://www.ccmo.nl/nl/uw-onderzoek-wmo-plichtig-of-niet.

A.2 When does my study impose 'actions or rules of behavior'?

Only if a study is medical in nature should the second WMO criterion be seen as relevant. In principle it might appear that any study with instructions ('play with your child for 10 minutes', 'fill in this questionnaire', 'tell us something about your holiday') imposes rules of behavior according to the WMO, but in practice the WMO refers to non-trivially burdensome or risky actions or rules of behavior, i.e. studies involving some non-trivial *infringement of the participant's physical and/or psychological integrity*. Examples are: burdensome experiments involving consistent very negative feedback, extremely long questionnaires, or months of daily self-reporting, studies in which false memories are induced or participants are asked about very stressful life experiences, or invasive studies in which for example blood is taken repeatedly.

By comparison: The Central Committee on Research Involving Human Subjects (which monitors application of the WMO) also mentions a few examples in which there is *no* question of burdensome or risky actions or rules of behavior:

- Research within educational psychology into the effect of specific forms of education on the retention and application of knowledge and skills by the student.
- Research in occupational psychology with reference to the construction and evaluation of occupational tests.
- Research in social psychology into the circumstances in which prejudices may be expressed in behavior.
- Research in experimental and social psychology into falling in love.

Unfortunately application of this second criterion is not simple for the individual Faculty of Humanities researcher, particularly as no linguistic research is discussed among the examples listed to clarify the WMO. However, the examples suggest that it must be a case of *substantial* burden; most Faculty of Humanities research will not belong to that category.

If you suspect that your medical study (criterion 1) is non-trivially burdensome/risky (criterion 2) you should submit the study for assessment by the METC. In cases of doubt you have two options: (a) request a preliminary assessment from the METC; or (b) submit the study directly for assessment by the FEtC-H. In the latter case the FEtC-H can help determine whether your study is subject to the WMO or not.

To reiterate, studies which are clearly burdensome/risky (criterion 2) but serve *no* medical aim (criterion 1) are *not* subject to the WMO, and therefore only require assessment by the FETC-H.

For further information we refer readers to the website of the Central Committee on Research Involving Human Subjects (www.ccmo.nl) and the associated e-learning site for clinical research (www.onderzoekswijs.nl).

A.3 What if my study fulfils both criteria?

In this case it is advisable to submit an application to the METC as quickly as possible as handling of such an application can take considerable time.

You should *also* always submit your study *to the FEtC-H* through the web portal. During the first screening in this web portal a quick WMO check is performed. If your study is subject to the WMO and has already been approved by a METC you can upload the METC approval immediately and then complete the FEtC-H application. If you do not yet have the approval of a METC you should save the FEtC-H application (i.e. save the partly filled in form in the web portal) until this approval has been obtained.

Appendix B. (Inter)national laws and regulations, codes of conduct and disciplinary codes

(inter-)Nationale wet- en regelgeving

- Europese Algemene Verordening Gegevensbescherming (AVG) (2018). https://autoriteitpersoonsgegevens.nl/en
- Dutch Act on Medical Research: Wet Medisch-wetenschappelijk onderzoek met mensen (WMO). https://wetten.overheid.nl/BWBR0009408/2019-04-02
- Helsinki Decalaration of the World Medical Association (WMA). https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/doh-sept1989/

Codes of conducts

- Netherlands Code of Conduct for Research Integrity, 2018 https://www.vsnu.nl/en_GB/news-items/nieuwsbericht/471-new-netherlands-code-of-conduct-for-research-integrity.html
- Code of Conduct for the use Personal Data (2005). https://www.vsnu.nl/files/documenten/Domeinen/Accountability/Codes/Gedragscode%20persoonsgegevens.pdf
- Central Committee on Research Involving Human Subjects (CCMO). https://english.ccmo.nl
- Faculty protocol data management (in progress)

Disciplinary codes

- American Political Science Association (APSA) Guide to professional ethics in political science. https://www.apsanet.org/TEACHING/Ethics
- American Anthropological Association 2012. https://www.americananthro.org
- Code of Ethics for Research in the Social and Behavioral sciences involving human participants http://ec.europa.eu/research/participants/data/ref/fp7/89867/social-sciences-humanities_en.pdf
- Economic and Social Research Council (ESRC) Framework for research ethics. https://esrc.ukri.org/funding/guidance-for-applicants/research-ethics/
- Ethics Code American Psychological Association (APA) 2010. http://www.apa.org/ethics/code.
- Gedragscode voor onderwijsonderzoekers (VOR) 2009. https://www.vorsite.nl/content/bestanden/vor-gedragscode_voor_onderwijsonderzoekers-2009.pdf
- New Brunswick Declaration on Research Ethics, Integrity and Governance
- UK Research Integrity Office checklist for researchers. https://ukrio.org/publications/checklist-for-researchers/
- Association of Internet Researchers https://aoir.org/ethics/

Appendix C. Criteria for *non*-standard Humanities research

The FEtC-H aims to assess studies as quickly and efficiently as possible, and therefore works with a distinction between standard and non-standard Humanities research (see section 2.5). The FEtC-H web portal decides *automatically*, based on several criteria, whether an application is likely to involve standard research (in which case accelerated assessment by 2 committee members can take place) or not.

A study is *never* standard research in the following cases:

a. The study is an intervention study.
b. The study makes use of adults incapable of giving informed consent.
c. The study works with passive informed consent.
d. The study observes participants in a *non*-public space and works with retrospective informed consent; see 3.2.2b.
e. The researcher works under cover in a managed *non*-public space (e.g. a digital discussion group), and takes part actively in the discussion and/or collects data which can be traced back to individual people; see 3.2.2c.
f. The study makes use of misrepresentation in the sense described in section 3.3.
g. The compensation for participants is inappropriate.
h. The study selects participants based on particular characteristics which might be associated with increased vulnerability, in any case including all DSM-classified syndromes (including aphasia, dyslexia, autism and dementia) and incapacitated people, minors, people with dementia, migrants, but also other possibly vulnerable people such as ethnic/cultural/ sexual minorities as well as homeless are imprisoned people.
i. The study uses psychophysiological measurements on children.
j. The study uses EMA (Electromagnetic Articulography).
k. The study involves multiple sessions, i.e. the participant takes part on multiple days (as in longitudinal research).
l. The researcher states that (or thinks it possible that) parts of the study or the study in its entirety is so burdensome that it could raise questions *despite informed consent having been obtained*.
m. The researcher states that (or thinks it possible that) the risks of later psychological, physical or other damage as a result of participation in the study are more than minimal.
n. The *total* duration of the tasks in the session, excluding breaks and other non-task elements, is *greater* than the limit for that age group (see table).

age group:	task duration limit
0 to 3 years old	20 minutes
4 to 5 years old	40 minutes
6 to 11 years old	60 minutes
12 to 17 years old	90 minutes

18 to 69 years old	120 minutes
70 years or older	60 minutes

N.B. These criteria for immediate *non*-standard research status may be adjusted by the FEtC-H at any moment on the basis of case-driven developments in insight. In the first year changes will certainly take place with some regularity, as this will be a learning phase in which the FEtC-H operates relatively conservatively (i.e. relatively many files will be discussed in committee meetings). *Always consult the* news *page on the FEtC-H website when planning your application and your research!*

The FEtC-H has made a conscious choice for digital screening on the basis of study features mentioned above, rather than for the procedure commonly used elsewhere in the country in which the researcher him/herself must work out whether his/her study falls under one of the various 'standard paradigms' already approved. The expectation is that feature screening will lead to a more principled and eventually *quicker* assessment procedure for researchers and the committee, particularly once the criteria have been optimized on the basis of progressive insights.