RESEARCH ETHICS REVIEW PROTOCOL
FACULTY OF HUMANITIES
VRIJE UNIVERSITEIT AMSTERDAM

VU UNIVERSITY AMSTERDAM
Faculty of Humanities

RESEARCH ETHICS REVIEW PROTOCOL

OF THE

FACULTY OF HUMANITIES

AT

Vrije Universiteit Amsterdam

Research Ethics Review Committee

Faculty of Humanities
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VU UNIVERSITY AMSTERDAM | Faculty of Humanities

Research Ethics Review Committee
Faculty of Humanities
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Foreword

In the Netherlands, the ethical review of medical scientific research with human participants has formally been laid down in law. Much of the research conducted within the humanities, however, does not fall under the definition used for medical scientific research and is therefore not subject to assessment by the medical ethics committees supervised by the Central Committee on Research Involving Human Subjects. Nonetheless, certain forms of research in humanities are increasingly expected to undergo a formal ethics assessment as well. Since May 2018 the General Data Protection Regulation (GDPR) and the General Data Protection Regulation (Implementation) Act have been in force with which the rules for the protection of personal data have been tightened. Following the example of other universities, the Faculty of Humanities at VU Amsterdam set up a Research Ethics Review Committee (ETCO) some years ago. This Committee offers solicited advice as to whether research within the faculty meets the faculty's ethical guidelines. These ethical guidelines are set down in this revised *Research Ethics Review Protocol*. All researchers within the faculty are expected to apply these guidelines. Future research, such as research using human subjects and personal data, must always be submitted to the ETCO of the Faculty of Humanities if there is any question of ethical issues. The ETCO will assess the research proposal on the basis of the *Research Ethics Review Protocol*. Research conducted within the faculty that falls under medical scientific research will still always have to be approved by the Medical Ethics Review Committee (MERC) of VU Amsterdam.

1. Basic principles, objective, method and composition of the ETCO

1.1 Primary objective of the ETCO

The primary objective of the Research Ethics Review Committee (ETCO) of the Faculty of Humanities at VU Amsterdam is to conduct an ethical review of and issue advice on research at the faculty that involves people, before that research is started. This concerns both research conducted within the faculty buildings itself and research conducted on behalf of the faculty (for example at a school, company or institution). Research by visiting researchers must first be reviewed by their own institution before it may be submitted to the ETCO of the Faculty of Humanities at VU Amsterdam.

1.2 Basic principles of the ETCO

The ETCO has drawn up binding rules for the Faculty of Humanities about how to conduct research and issues advice on the admissibility of research. Basic principles are generic criteria for ethical research as adopted in the *Declaration of Helsinki*[1] and by the *APA*[2].

In more specific terms, the ETCO uses the following basic principles as regards scientific research:

1. Research is set up and conducted in accordance with the applicable laws and regulations.
2. Personal data is processed in accordance with the applicable laws and regulations. That includes at least the General Data Protection Regulation (GDPR) and the General Data Protection Regulation (Implementation) Act.

[1] Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects, adopted in 1964 by the World Medical Association and revised in 2008. Central elements are the guarantee that participants (decisionally competent or impaired, whether or not in a relationship of dependence to the researcher) may terminate their participation at all times without consequence. The full document can be viewed here: http://www.wma.net/en/30publications/10policies/b3/17c.pdf

[2] American Psychological Association; the most recent ethical rules and procedures can be found here: http://www.apa.org/ethics/code/index.aspx

3. Researchers bear responsibility for ethical methods in research conducted by others under their supervision or responsibility. In preparing the study, the acceptability of the study is assessed in the light of current ethical principles. Researchers are expected to have the ETCO assess the ethical acceptability of their study.
4. Researchers and their assistants only carry out the tasks for which they underwent the appropriate training and preparation.
5. When conducting research outside their workplace, researchers will ensure that they have the consent of the host institutions or other relevant organizations before the research is conducted. In this context, the study must meet the requirements set by the faculty and the host institution.
6. Researchers take measures ensuring that the rights and wellbeing of the participants and other people connected with the study are not violated.
7. When research is conducted with participants who have specific problems, the researchers must address these problems before conducting the study. In this respect, they will consult with experts in the field.

1.3 Composition of the ETCO

The ETCO consists of a chairperson, a secretary and a number of members who have such a range of expertise as to cover the different types of research conducted within the research institutes working in the Faculty of Humanities, i.e. the *Network Institute* (http://networkinstitute.org/) and CLUE+ (https://www.clue.vu.nl/en/index.aspx), as well as an expert in the field of Ethics (from the Department of Philosophy). Lastly, the faculty privacy officer for research is part of the ETCO. The Faculty Office of the Faculty of Humanities provides the Committee's secretary. The ETCO meets on an ad hoc basis as deemed necessary. At those meetings, the ETCO tightens its policy and discusses specific research projects that have been submitted through the application procedure.

1.4 Criteria to assess research

The criterion of person-specificity means that all research within the faculty relating to participation by or data from persons, whether implicit or explicit, must be assessed against the criteria formulated by the faculty. That also applies to research conducted in the context of education and for research conducted with the aid of the internet (online experimental programs). If students conduct research involving people or personal data for a tutorial, the lecturer will point out the importance of collecting and analysing that data securely. At the end of the tutorial, this data will be destroyed, unless the lecturer wishes to use it to carry out further research. In that case, the lecturer is responsible for the proper handling and storage of that data and for requesting permission from the Ethics Review Committee for their research plans concerning that data and the method of storage during and after the proposed research.

If a student wishes to conduct research with people and/or personal data for their thesis, the student is obliged to follow the guidelines for secure and responsible working practices and storage of personal data. The student must express agreement in writing (preferably in the thesis agreement) to compliance with the GDPR and RDM guidelines. The student consults with their thesis supervisor when selecting the software to be used to collect and analyse this data. The student is required to archive their own thesis by uploading it to the University Library's website. The University Library will also be asked to provide appropriate storage facilities for the research data and metadata relating to the theses. Research that is conducted in the context of a PhD project must be submitted for assessment by the PhD candidate conducting the research.

Where it concerns analyses of existing data sets and data that does not involve people or personal data, the researchers are expected to determine themselves whether their proposed research must be reported to the ETCO. If required they can use the self-check form and

the flowcharts (Flowchart #1 & #2) that are available online.

A researcher with an appointment or admission at the Faculty of Humanities at VU Amsterdam is always primarily responsible for the research. If the research is conducted by a trainee or hired employee, a faculty staff member must bear the responsibility. Researchers sharing an appointment with another institution must, before they begin, submit their proposal with the institution responsible for the research to be conducted.[3] The researcher who submits the research with the ETCO is referred to below as the project leader. The researcher with primary responsibility must submit the research proposal electronically for assessment, using a platform set up specifically for that purpose. The online form can be found here.

The Committee strives to distinguish between cases for specific assessment and standard research studies that can be handled through fast and preferably electronic procedures, to avoid frustrating researchers and teaching with time-consuming procedures. In those cases where researchers make new or non-standard proposals, they should be prepared to account for their proposal and for a certain amount of time involved for the procedure by the ETCO.

The Ethics Review Committee keeps an overview of submitted applications with the advice relating to research with personal data carried out within the faculty.

1.5 Term for providing advice by ETCO

Research that is to be handled by the ETCO in a meeting (and that therefore is not subject to an abridged procedure) will be handled at the next regular meeting or earlier if there are compelling reasons. The ETCO strives to issue its advice within ten working days. Their advice on the application is always issued within two months (unless further information was requested and that information was not supplied on time; the term will then be extended accordingly).

1.6 Assessment procedure

The ETCO strives to streamline the assessment procedure as much as possible. Research studies that are hardly different from previously conducted research - in other words, standard research studies as have been conducted within the Faculty of Humanities for many years now - are only assessed in broad outlines. Examples are studies where the stimuli material, type of questionnaire or type of experiment are not fundamentally different from previous research studies approved by the ETCO.

For that reason, the ETCO uses descriptions of standard studies, which are supplied by the individual sections and/or Principal Investigators groups. Project leaders who indicate on their application that their research falls within the description of this kind of standard research study subsequently follow an abridged application procedure. The descriptions of standard research studies are regularly updated, for example in the context of evaluation and self evaluation or quality inspections or when this is required in the view of the chair-holders or Principal Investigators.

In the case of a standard research study, it is sufficient if the project leader submits the research with the ETCO by filling out the registration form and submitting the project proposal, the information document and the consent form pertaining to the research. The ETCO then checks the information and if it is in agreement, the study will be given a positive advice, without the project being discussed in

[3] Please note, when personal data is processed, it is very well possible that both institutions bear responsibility for compliance with the privacy legislation (GDPR and the General Data Protection Regulation (Implementation) Act). In that case, it is important that the institutions make mutual agreements on this. For support in this regard, please consult the faculty's Privacy Champions.

great detail at the meeting. An overview is kept of the submitted applications with the advice issued.

In all other cases, if the research does not fall within the customary context and procedures, the research will be discussed at the meeting. In that case, the registration form must also be filled in and the project proposal, information document and consent form belonging to the research must also be presented. This is supplemented with details about where the research differs from standard research and all further information the ETCO needs to formulate its advice.

2. The procedure for submitting a project with the ETCO

2.1 Determining research discipline

To properly issue advice on the research project, it is important to know within which interdiscipline or subdiscipline a certain type of research study will be conducted. Although the researchers working within that discipline generally have extensive experience with this type of research study, that study must still be registered. Research that has never been conducted in a certain discipline before merits closer attention from the ETCO.

2.2 Duration of the positive advice from ETCO

In principle, research projects are submitted for assessment in their entirety. The responsible project leader is in principle free to determine for which parts of the research a separate application will submitted. However, in those cases where these parts require a different methodological approach, it is important that a clear description is given of the separate parts that the project will consist of. The positive advice issued by the ETCO is given in principle for a five-year period. If the research is continued after those five years, the project leader must turn to the ETCO again.

2.3 External provision of grants

Research studies submitted as project proposal with an external funding body are generally submitted for review after selection by the funding body. If requested by the funding body, the project proposals may also be assessed by the ETCO prior to submission. In a graduated submission procedure (submit proposal - selected for elaboration - final submission), the assessment may be made in the elaboration phase prior to final submission.

2.4 Required documents

The project leader submits an information document: a description of the research in writing (in Dutch or English) as it will be submitted to the participants. The information document must clearly indicate to the participants in the research study what that study involves in terms of workload, risks and discomfort. This document must also include other provisions (see under 3.7 'Informed consent') regarding remuneration, voluntary participation, screening, anonymity, the processing of the participant's personal data,[4] etc. The project leader also submits a consent form which the participants will sign if they are willing to cooperate with the research study after having read the information document. The flowcharts available on the ETCO's website can be used to determine which documents are required. For lab research, the consent form must always be signed by the participant or the legal representative in advance. The consent form may also regulate the transfer of copyright or other rights. Issuing misleading information to participants in the interest of the research is not permitted.

2.5 Abridged and comprehensive procedures

The project leader fills in the application form and submits it, together with the project proposal, the information document, the consent

[4] If the study processes personal data, the information document must at least contain the information referred to in Article 13 of the GDPR. See also section 3.7.2.

form and other relevant documents. Based on these documents, the secretary will advise whether the research can go through an *abridged procedure* at the ETCO, which means it will be handled by the secretary and a second member of the ETCO, or an *comprehensive procedure*, which means it will be handled at the meeting. However, the research study may fall outside the jurisdiction of the Faculty of Humanities' ETCO, mainly because the research falls under the Dutch Medical Research Act. In that latter case, the research study must be assessed by an accredited Medical Ethics Review Committee, for example at our sister faculty, the Faculty of Medicine at Amsterdam UMC, VUmc location (see below under section 3.1) As soon as the registration form and relevant documents have been submitted, the project leader will receive a confirmation by email.

3. Provisions for research within the Faculty of Humanities

3.1 Assessment by ETCO or MERC?

Research within the Faculty of Humanities is rarely clinical in nature. However, it must first be established whether the research should be assessed by an accredited Medical Ethics Review Committee (MERC). In that case, the Faculty of Humanities' ETCO is not authorized to issue advice on the research, and it should be submitted to an accredited MERC for assessment (for example at Amsterdam UMC, VUmc location, or at another institution involved in the research). The criteria used to establish whether a research study should be assessed by the ETCO or a MERC can be found below. The relevant rules and regulations in this respect are set out in the Dutch Medical Research involving Human Subjects Act. There is also a Central Committee on Research Involving Human Subjects. The law prescribes that research falls under the Medical Research involving Human Subjects Act if both of the following criteria apply:

1. It concerns medical research.
2. The participants are subjected to actions and/or a certain conduct is imposed on the participants.[5]

The first criterion must be answered with yes if a healthcare institution is involved in the research in one of the following ways:

- one or more of the healthcare institution's staff members are involved in the research as a client or provider/party carrying out the study, or
- the research is conducted within the walls of the institution and, given the nature of the research, would normally not be conducted outside the walls of the institution, or
- patients/clients of the institution participate in the research study (in the capacity of medical treatment).

If criterion 1 is not but criterion 2 is answered with yes, it means that the research study must be assessed by the ETCO.

To be more specific, research falls within the scope of the ETCO if it meets one or more of the following criteria:

- People are subjected to actions
- Rules of conduct are imposed on people
- The personal data of people is collected and stored

Take for example linguistic research where linguistic functions such as speech and language comprehension as well as speech and language production are examined, and where in some cases the study looks at how these processes can be detected in the brain. That requires the use of psychophysiological methods that are also used in medical research, for example an EEG or FMRI. However, if applied as stated under 3.1.2., the risk of these methods is negligible and will in all likelihood not lead to a negative advice. Small variations on this type of research must

[5] Medical Research involving Human Subjects Act Section 1(1)(b)

nonetheless always be looked at closely as they could have ethically relevant consequences. A second example: research by Communication and Information studies and Literary studies looks at the effects of textual and communication products on people; an impact on the wellbeing is generally not expected. Finally, historic and practical philosophical research sometimes uses informants as a source; in this case also, no health impact is expected. The research in all these disciplines is conducted outside of the medical field, but does involve working with human subjects and/or storing personal data; for that reason it must undergo ethical review by the ETCO.

3.2 Research within the Faculty of Humanities

Criterion for assessing research within the Faculty of Humanities follows from the above:

Does it concern research involving people who are subjected to actions or on whom rules of conduct are imposed and/or whose personal data is collected and stored?

Broken down into measuring methods, we distinguish four main types of research to which this criterion applies.

3.2.1 Registration of behaviour

These are experiments where participants perform a task where stimuli are given in one or more sensory modalities. The participant is placed in a set-up consisting of instruments that measure behaviour. The research never takes longer than four hours (or two hours for under 18s, one hour for under 6s or 30 minutes for under 2s). The participant is never seated in the same posture for more than 60 minutes. The participant does not take part in the study for more than three times a week. The stimulus material and/or behaviour registration may involve some workload for the participant and cause some discomfort, but this may never result in damage.

3.2.2 Psychophysiological registration

These are measurements where bodily functions are registered under the influence of stimuli offered in one or more sensory modalities. The study is carried out in accordance with accepted standards of hygienic work in laboratory environments. The participant is never seated in the set-up for more than two hours and is never seated or lying in the same posture for more than 60 minutes; the maximum consecutive period in which the participant may not move does not exceed 20 minutes. Physical discomfort is kept to a minimum. The participant is not put in the scanner more than three times a day (children up to the age of 12 no more than two times a day) and is not involved in this type of registration for more than twice a week.

3.2.3 Interview

This includes methods where in an interview or by a written questionnaire the person participating in the study transfers opinions, responses, memories or evaluations to the researcher, who subsequently interprets these in a qualitative and quantitative way and publishes on this topic. That includes the research methods that open up and distribute personal data from deceased people through research of sources, which could have ethical consequences for the direct next-of-kin. In all cases, discomfort could occur by disclosing personal data that reveals the identity of individuals.

If the project leader believes that providing an information form, having a consent form signed and (if applicable) providing a debriefing form is not possible in the research study applied for, they should argue why this is not possible and explain how the researcher will guarantee the integrity and anonymity of the participants where it concerns the collection, storage and scientific use of data (see also the concluding paragraph of provision 2.4).

3.2.4 Data registration of media

Weighing the discomfort to people and the protection of people's privacy are also points

for attention in studies into internet data. In accordance with the GDPR, personal data from 'open' sources such as Instagram, Facebook and Twitter may not be used freely, despite the fact that the author has already made information available online that can be traced to them. Each item of personal data processed must meet the requirements ensuing from the privacy legislation. 'Data scraping' using personal data is therefore not allowed out of hand and research where this type of data will be used must therefore be submitted to the ETCO. There are both ethical and legal aspects to consider, such as copyright and the right of reproduction enshrined in it to collect and store the data that is available on the internet and that is used for research.

The following section sets out the provisions that apply to all methods of measurement. (If a document has been drafted as described in section 2.4, sections 3.3, 3.7 (including subsections) and 3.9 do not apply).

3.3 Selection of participants

A standard participant is a healthy adult from 16 years of age and a decisionally competent volunteer who participates in the study and does not receive a disproportionate remuneration for that participation and who is not in any way dependent on the researcher or the person conducting the research study. The study may not take place with people who, outside of the study, are in a subordinate position to the researcher, e.g. students with whom the researcher has a direct teaching relationship.

In addition to adult, decisionally competent participants, the study may also use underage participants. Specifically these are babies or children under the age of 16 who participate in the study with the consent of their parents or guardians on a voluntary basis. As this type of research will never meet the criterion of decisional competence on the part of the participants, it must always be submitted to the ETCO; an important question for the ETCO in that case is whether the study cannot be conducted using adults instead of children.

The researcher may approach an institutional environment (university of applied sciences, healthcare institution, company, etc.) for participation in the study, at which the management of that institution will then approach the residents/members/students about participation. In this case, it must also concern adults and the participants must sign the consent form (see under 3.7) individually or jointly on the same form.

As regards the participation of non-adult or decisionally incompetent people, see under 3.7. The Faculty of Humanities has taken out collective insurance for participants in a study to cover all risks of accidents during the stay in the laboratory and the trip to and from the laboratory. The liability insurance offered by VU Amsterdam provides cover, within the framework of the policy terms, for non-invasive studies, on the condition that the Medical Research involving Human Subjects Act does not contain specific requirements for the insurance of participants. This cover includes both damage to equipment and damage to/by the participant and experimenters. This cover applies to researchers and visiting researchers at the Faculty of Humanities. In addition, this insurance applies for external research, commercial if applicable, as long as this research is conducted by VU staff. If there is an indication under the Medical Research involving Human Subjects Act, the responsible researcher must submit a timely application for personal insurance for participants. This application must include the research proposal (Medical Research involving Human Subjects Act application). For more information about corporate insurance within VU Amsterdam, please contact the VU Corporate Finance Department.

3.4 Screening of participants

If required by the study, participants must be screened for characteristics relevant to the research study. This could be hearing tests in studies into speech perception, or questionnaires of neurological or psychological characteristics for EEG, or claustrophobia for FMRI research. In the case of research involving fMRI, special screening procedures always apply to keep the risks of these experiments negligible. Furthermore, certain inclusion/exclusion criteria may be used, for example a certain age range or certain range in language proficiency scores, sometimes with the aim of finding a match with other participants.

3.5 Chance findings

Some research methods that measure bodily functions can result in chance findings that may be of importance to the participants involved. These may include an abnormality on an FMRI, a language acquisition disorder, or visual, auditory or cognitive abnormalities. For this research method, a provision must be included in the consent form that informs the participants of the procedure to be followed in that case. The participant in those studies must fill in the name of their GP or GP's practice, who is then notified in the case of any relevant findings. If the participant does not have a GP, they must consent to the fact that the university doctor, or the occupational health physician if applicable, is notified. The participant must agree to this procedure by signing a separate clause on the consent form.

The *procedure* in the case of a chance finding is as follows. The participant may not be notified of the chance finding by the project leader. For that reason, the participant may never view their own test results (e.g. MRI scan, language test, audiogram, dyslexia test) after the measurement, even if there is no chance finding. The project leader leaves the relevant test results in the registration system. The project leader passes on the chance finding to the head of research and includes the contact details of the GP or authorized medical or other body as provided by the participant. It may also happen that a study yields findings that give a worrying picture of the participant which may be stressful for the researcher conducting the study; in that case the researcher may consult a psychologist associated with the research institute.

3.6 Voluntary participation

Regardless of the selection method used, each participating person is free to leave or halt the study at whatever time and for whatever reason without adverse consequences for the study or otherwise. Participants may also decide, after the research study has been completed, not to have their data included in the study. Consent can therefore be withdrawn at any time and this should be stated on the information document. Withdrawal of the consent can in principle not be done retroactively. A 'right to erasure' invoked by a participant may be refused if that severely hinders or renders the research impossible and if sufficient measures were taken to guarantee privacy. In that case, the personal data does not need to be erased but the data may not be used for further research. The reimbursement 'earned' till then is paid out in proportion to the length of participation.

People approached individually or as a group may not be pressured (nor by peer pressure) into participating, nor may a remuneration be promised that is higher than the one established in advance.

3.7 Informed consent

Every participant signs a consent form for each research study. That means that the participant consents to the research being conducted, and that their consent is based on full and accurate information (informed) as regards the procedures to be expected, discomfort, risk, duration, objective, processing of personal data[6], etc. If participants cannot be expected to grant their informed consent (participants under the age of 16, mentally impaired people), the consent

[6] If the study processes personal data, the information document must at least contain the information referred to in Article 13 of the GDPR.

form must be presented to the authorized representative of the participants. These studies never fall under the abridged procedure and must always be handled by the ETCO. If the participant is under 16, one of the following options applies:

a. if participants under 16 are supervised by their parent(s) or guardian(s) during the study, the consent form is filled in and signed by the parents or guardians;
b. if the study takes place within a host institute where children are residents, and the management of that institute is authorized to decide on participation in the study without consulting the parent(s) or guardian(s) (which fact will have to be proven to the ETCO), the consent form is filled in and signed by or on behalf of the management of the institution;
c. if the study takes place within a host institute where children are not residents (such as a school), and if it can reasonably be expected that an active informed consent procedure as described under a. will not yield sufficient positive response, the host institute may use the general informed-consent procedure. In this kind of procedure, the management of the host institute has asked the parent(s) or guardian(s) in advance for general consent to allow their children to participate in research conducted within the institute. The data of children whose parent(s) or guardian(s) have not given this general consent must be removed from the study.

3.7.1 Specifications regarding the consent form and information document

Prior to the study and during the recruitment of participants, the researcher will inform the participants of what they could expect during the study. Based on that information, the participants are explicitly requested to consent to their data being used for the study. Prior to reading the *information document* pertaining to the study and prior to participation in the study, the participants sign a *consent form*. The information document and consent form may be two separate documents, or be incorporated into one.

Both the information document and the consent form must be written in such a way as to be intelligible to the target group, even if this target group is semi-literate, and should always avoid the use of jargon or uncommon abbreviations.

3.7.2 Information document

The information document includes as a minimum:

a. The name, address, telephone number and email address of the project leader, who acts as point of contact for participants with further questions.
b. The name, address, telephone number and email address of the ETCO secretary, who acts as point of contact for participants with complaints.
c. The objective of the study. If the objective of the study cannot be revealed because of the research question, an explanation will follow as soon as possible after the study has been completed, in a debriefing where the possibly adverse effects of the deception are explored. The researcher may never deceive the participant about important aspects of the study that could influence the willingness to participate, such as risks, discomfort or adverse consequences.
d. The procedure of the study, the actions to be taken, etc. Based on this information, the participant must be able to make an informed decision about the expected discomfort and duration and any risks (even if negligible) of the study.
e. All factors that may influence the willingness to participate, such as risks, discomfort or adverse consequences.
f. The remuneration for participating in the study and under which conditions it is paid out. If professional services (such as treatment or education) are offered by way of remuneration for participation in the study, the researcher must clearly indicate to the

participant what the nature of those services is, as well as the risks, obligations and restrictions that the services entail.

g. The categories of people excluded from participation in the study because of an increased risk or discomfort. These may include people with claustrophobia for the FMRI experiments, people with a tendency to faint for the emotional-stress experiments, pregnant women for studies into substances such as alcohol, etc. (this is unrelated to the screening necessary for some categories of research, see *Screening of participants for psychophysiological registration*).

h. A statement about the extent to which the anonymity of the participants in the study is guaranteed and how the data will be made available to third parties. Consent for making personal data available to public data collections must be indicated directly on the consent form. Anonymity must be ensured. In the case of audio or video clips or text registrations for language corpora, it must be made clear that anonymity cannot be guaranteed, while it is also explicitly made clear who the potential users will be and what the material will potentially be used for. Such material may never be made public without the prior express consent of the participants.

i. The statement that participation is always voluntary and that the participants may, without giving reasons, refuse to participate in the study and break off their participation at any time and even afterwards refuse to have their data used for the study, whether or not retroactively for the data already processed. This will always be without any adverse consequences for the participants, for their study results, etc. The reimbursement 'earned' till then is paid out as normal in proportion to the length of participation.

j. If there is a possibility of chance findings (see under 3.5), the procedure to be followed must be included. *The participant must explicitly agree to this procedure by placing their signature separately on the informed consent form.*

k. Finally, based on the General Data Protection Regulation (GDPR), the information document must contain the following information as a minimum:
   a. the name of the data controller (VU Foundation) and any organizations also responsible;
   b. the contact details of the Data Protection Officer at VU Amsterdam and any other organizations involved;
   c. the categories of personal data processed;
   d. the purposes for which this personal data is processed and the grounds on which it is processed;
   e. the recipients or categories of recipients of the personal data;
   f. where applicable, the intention to transfer the personal data to countries outside the European Economic Area (EEA) or international organizations, and how that transfer is safeguarded;
   g. the retention period of personal data or, if that proves impossible, the criteria to determine that period;
   h. the rights of those involved, including withdrawing consent, objecting and filing a complaint with the Dutch Data Protection Authority. Any other rights (inspection, rectification, data deletion and restrictions of the processing) often do not apply to scientific research;
   i whether computerized decisions are made.[7]

Retention periods (explanation to 3.7.3(k)(g.))

The GDPR does not mention any concrete periods in numbers, but does expect the researcher to indicate specifically how long the data will be kept and that it will be deleted after that period expires. Longer retention for archive

[7] The Privacy Champions at the faculty provide primary support to comply with requirements arising from the General Data Protection Regulation (GDPR) and the General Data Protection Regulation (Implementation) Act. 4 Medical Research involving Human Subjects Act Section 6(2).

purposes in the public interest, for scientific research or for statistical purposes is permitted, on the condition that appropriate safeguards are put in place to protect the people involved. VU Amsterdam applies a period of at least ten years to retain research data, calculated from 1 January of the year following the year that the study was published. This is important both for verification purposes and for potential follow-up research. Depending on the nature of the data, these two objectives may coincide. This will not always be the case for privacy-sensitive data and thus other retention periods may apply, in accordance with legislation in this area.

3.7.3 Consent form

The consent form to be signed by the researcher and the participant states that the participant was informed about, and fully understands, the contents of the information document (if the information document is separate from the form to be signed, this form must contain an unambiguous reference to the relevant information document). If there are additional provisions (screening, chance findings, debriefing), the participant must sign separately for consent to these procedures and fill in the required information (for example, their GP's name and address). The form also lists all contact addresses as referred to in the information document (see a and b above). On request, participants are given a copy of the form and of the information document to take home. Examples of the consent forms can be found on the ETCO website.

In the following cases, an exception may be made to the above informed consent procedure:

a. Research where a questionnaire or experiment is provided without the project leader meeting with the participant, such as when a questionnaire is sent by post or filled in at home, or when a questionnaire or experiment is provided through a website. In that case, the researcher will provide the above information through a cover letter or via the website. Participants will be asked to give their explicit consent to their data being processed in the way described in the information document. In this case as well, the participant is free to decide at any time not to continue with the questionnaire.

b. If the participants are unable to read or write, equivalent verbal consent must be obtained in the presence of a witness and these statements must be recorded on video. These types of study are always discussed separately by the ETCO and may never be handled in an abridged procedure.

3.8 Anonymity

Data obtained from research may not be made available to third parties (in publications, or shown in presentations or in mutual consultation) in such a way that the results or other findings can be traced back to a certain participant. One exception to this are the cases when results from a previous study are put forward as a selection criterion for participants. In that case, the data may be exchanged in encrypted form where possible and will in no case be made available to persons other than those involved in setting up the research studies. Naturally, the data will then be pseudonymized after collection and always published etc. anonymously.

In some cases, it may be useful if the results of certain participants are used for educational purposes (teaching, conference presentations, scientific documentary, etc.). It may also deliberately be the purpose to collect and store data that can be traced back to an individual, such as when compiling language and media corpora. If that poses a risk for the participants' anonymity being violated, as is the case in photo, video or audio recordings (but perhaps also in the case of psychophysiological registrations), explicit consent must be asked in advance, before the data is used for any other purposes, before or after the original research study. The use of this data is only permitted for those purposes for which the participants

(or their authorized representative) gave their consent *separately* to the researcher, if possible in writing, but verbally in the case the participant is unable to read or write. All data in which the participants can be identified are managed in accordance with the applicable laws and regulations connected with privacy; see the related topic 'legal context' (3.11).

3.9 Feedback, deception and debriefing

It is advisable to give participants feedback after the study about the objective and set-up of the study in which they participated.

If the study involved deception, giving a debriefing is compulsory. Deception of participants is only permitted if it is necessary for the study that the participants do not have an accurate picture of the precise intention or procedure of the experiment. Deception is taken to mean providing inaccurate information to the participant or the unnoticed registration of the participant. In general the following applies in the case of deception:

a. In principle, deception is not permitted for the information which based on the GDPR must be given to the participant in connection with the processing of their personal data (see section 3.7.2 (k)). In certain cases, it may not be possible to provide the information in advance because of the deception, such as a detailed description of the objectives for which the personal data will be processed or an overview of the personal data to be processed. In those cases, the faculty's Privacy Champions will be consulted about how to ensure that the required information is provided where possible in advance and which additional information may be given afterwards.
b. Deception is not permitted when it concerns information about any risks connected to participation; deception is only permitted if there is no possibility of answering the questions without deception.
c. After the deception, there is full feedback, referred to as the debriefing of the participant, about the way in which the participant has been deceived. If in all reasonableness negative effects of the deception are to be expected, the debriefing must take place immediately after the experiment ends (for example if incorrect negative feedback is given about the scores). The debriefing is set up in such a way that the temporary negative impact on for example the participants' perception of themselves or mood is removed by the debriefing. If no temporary negative effects are to be expected, the debriefing may be held at a later time, but no later than two weeks after the experiment or sub-experiment is terminated; this means that longitudinal research, in which the deception continues for a longer period, must always be submitted to the ETCO because as a rule the debriefing should take place as soon as possible after the deception.

3.10 Recruitment of participants

When recruiting participants, it is not necessary to provide all the information about the study (as in the information document). However, the following must be made clear at the time of recruitment:

a. Whether there are any pronounced negatively perceived procedures that entail considerable physical discomfort, of that may be suspected in advance to prevent a number of people from participating.
b. Whether materials are used that could be offensive or unsuitable to certain groups of people, for example based on a religious belief. These may include racist or explicit photos or films, use of alcohol, etc.

3.11. Legal context

The ETCO assesses the submitted research studies on the basis of ethical standards. Where the provisions of this protocol do not provide for a decision criterion, the context provided by the current laws and regulations applies. Researchers will always work within the legal context and are expected to be familiar with

current laws and regulations and to comply with them.

Researchers should in general behave appropriately and observe the current laws and regulations as regards the storage of data and the provision of data to other researchers.

Copyright and/or portrait rights may apply for individual participants in the case of audio or video recordings or recordings of text productions. In that case, participants should, depending on the researcher's purposes, also indicate their consent on the consent form for the use and/or archiving of recordings for (1) research, and/or (2) public presentation at conferences, etc., and/or (3) publication on the secured website of journals, and/or (4) publication on, for example, the internet. This form can easily be combined with the provisions under 3.8 ('Anonymity').

Where it concerns data on the internet and used for research, both copyrights and reproduction rights are important. If the author of the data has the property rights (as in the case of emails or websites), prior written consent is required from the author to reproduce the data or parts of the data. If the copyright belongs to the internet company that makes the data available online (social media, such as Facebook or Twitter), prior written consent from this company is required from the author to reproduce the data or parts of the data. As these companies generally decline to give permission, this data can only be made accessible in scientific publications and presentations by referring to the internet locations.

3.12 Teaching and research-ethical context

The studies submitted to the ETCO for assessment are subject to the teaching and research standards of the institution and the involved research institutions as a guiding principle. The ETCO holds the view as a basic principle that, in the expectation of the research institution, the submitted research will yield new and important insights and/or teaching competences for students and further expects that the research is conducted under the supervision of a qualified individual, that the person conducting the study has been well trained and is competent, and finally that all those involved in the research are familiar with and act according to the institutional rules of research ethics.

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