Ethical assessment of empirical research into human behaviour at the Utrecht Institute of Linguistics OTS (UiL OTS) Utrecht University

REGULATIONS

All researchers involved in UiL OTS 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)

Faculty Ethics Assessment Committee - Humanities (FEtC-H)
Linguistics chamber
UiL OTS, Faculty of Humanities
Utrecht University
Version October 2019

Faculty Ethics Committee
FEtC-H
Humanities
Utrecht University

1. Introduction

1.1 Why ethical assessment?

Ideas on quality control of empirical research into human behaviour have changed substantially over the years. Researchers are increasingly expected not only to weigh up the ethical acceptability of their research for themselves, but also to present it to an authorised 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 organisations 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 UiL OTS Ethical Assessment Committee for Linguistics (hereafter ETCL) in the Faculty of Humanities has been established to support UiL OTS 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 ETCL 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 What kind of studies should apply for assessment?

Every new study in which data on human behaviour is collected from one or more participants ('human test subjects', 'respondents', 'informants', 'observees', etc.) and which researchers carry out in the framework of their UiL OTS affiliation under the flag of the institute must be submitted to the ETCL *before* the research is carried out. This applies to studies in which the research participants are assigned special tasks (e.g. 'play with your child as you would at home for 10 minutes', 'fill in this internet survey at home', 'read these stories carefully', 'tell us something about your holiday', etc.), as well as studies in which the participants are observed in their normal 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 behaviour should be broadly interpreted, ranging from spontaneous behaviour in face-to-face interaction or on social media to behavioural, physiological and eye-movement reactions in laboratory tasks.

All research that is carried out at the lab, or with the help of the UiL OTS database of participants, must be submitted at the ETCL. This includes studies carried out by a guest researcher where (possibly at first) no member of the UiL OTS institute is involved. If the study is already reviewed by the guest researcher's home institution, the study still needs to be registered at the ETCL. Ethical approval granted by the guest researcher's home institution does not in principle guarantee ETCL approval, but it may help accelerate the ETCL process.

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 ETCL. 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 ETCL for a preliminary assessment of research for a subsidy application (section 2.9.3).

1.2.1 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 supervised by an UiL OTS researcher in his or her role as a teacher, the specific situation determines whether this must be presented to the ETCL, and if so when. The following situations are distinguished:

a. For research supervised in the context of education but also forming part of a research project carried out under the flag of the UiL OTS (i.e. involving publications through the usual scientific channels such as journal articles, not just a BA or MA dissertation on Igitur for example) the following applies: (1) where possible these studies should always be presented to the ETCL *in advance*, (2) where education-related conditions make this impossible the study should be presented to the ETCL *as soon as possible*, and in any case *before beginning to write up for a scientific publication* (with the exception of the cases mentioned under point b). 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 ETCL.

   Beware: Research supervised in the context of education that has been presented to the ETCL – 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 (e.g., the informed consent) can no longer be made. In such case, the ETCL only offers an advice: "If this study were assessed beforehand, it would have (not) met with approval".

b. Since familiarity with ethical assessment is an important component of the training of a researcher, thesis research in the Research Masters' in Linguistics must *always* be presented to the ETCL. Educational conditions (and the desired level of detail of the application) will sometimes make it impossible to receive approval from the ETCL before data collection, but the application should still be *submitted* before data

collection (with work beginning on the study pending a decision from the ETCL). Supervisors should take particular care in monitoring the ethical side of a thesis study that has been presented to the ETCL but is still pending approval.

c. Research carried out *exclusively for pedagogical purposes* in the context of a BA, MA or Research Master's course (i.e. where UiL OTS researchers are involved only for their course requirements) does *not* require presentation to the ETCL (unless the research is carried out at the lab or with the help of the UiL OTS database of participants, see also section 1.2) . 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 ETCL regulations as well as the informed consent forms available through the ETCL website.

For student projects for which the UiL OTS 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 ETCL in connection with burden or risk to participants, the exceptions under points *a* to *c* do *not* apply; such studies can *only* begin after ethical approval.

1.2.2 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:

a. 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 ETCL 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.

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

The ETCL 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.

1.3 Assessment by the ETCL or METC?

UiL OTS research with a *medical* aim *and* in which the participant is provided with rules of behaviour 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 offered for assessment by a regional Medical Ethical Assessment Committee (METC). For UiL OTS 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 behaviour 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 ETCL, to comply with the institute's requirement for registration of studies, and because only then can UiL OTS's own ethical committee establish that the institute can take responsibility for it. The ETCL assessment will tend not to differ from that of the METC in practice, and after approval by the METC the ETCL will generally be able to grant approval almost immediately.

For all UiL OTS research involving human subjects which is *not* assessed by a METC (legally or in practice), internal assessment by the ETCL is sufficient.

1.4 What does the ETCL focus on in its assessment?

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

(1) *Adequate informed consent.* Voluntary participation is central to research on 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.

(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.

(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.

The ETCL 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 focus is on guarding 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] and, for medical research, in the *Declaration of Helsinki*,[3] and guidelines of the Central Committee on Research Involving Human Subjects.[4] Since more or less all of these guidelines must be interpreted in context, the ETCL 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 ETCL 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.

2 How does ETCL assessment work in practice?

2.1 What precisely should be registered?

Every new UiL OTS study with human participants which does not fall under the exceptions discussed in section 1.2 must be submitted to the ETCL for assessment before work on the

[1] http://www.apa.org/ethics/code.

[2] http://ec.europa.eu/research/participants/data/ref/fp7/89867/social-sciences-humanities_en.pdf

[3] http://www.wma.net/en/30publications/10policies/b3.

[4] See http://www.ccmo.nl.

study is started. During the application, which is facilitated by a special ETCL 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 ETCL the information letter and declaration of consent (based on the standard UiL OTS formats for informed consent).

When registering a study with the ETCL, a good understanding of the following definitions is indispensable. Firstly, with respect to the *types* of research, the ETCL 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.

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

Task-based research. 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', 'tell us about your holiday', 'play with your child for 10 minutes as 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, or 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 ETCL, is defined as follows: a piece of research in which new data is 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 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. In the ETCL context 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.

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 ETCL. 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 ETCL website.

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

The final assessment will be given by the ETCL 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 is always registered by a **researcher with final responsibility**, a researcher holding a PhD and affiliated with the UiL OTS who bears final responsibility for the study within the UiL OTS, 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 in this sense. 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 ETCL.

UiL OTS 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 UiL OTS should be registered with the ETCL by an UiL OTS staff member involved in the study, or, if *no* UiL OTS 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 ETCL?

In order to make the assessment procedure as streamlined as possible for the researchers and the committee, the ETCL works with a web portal, a special digital environment where the study can be registered. When a new study is registered through the ETCL portal, the researcher specifies all ethically relevant aspects of the planned study using a list of

questions, and the information letter and associated declaration of consent are submitted to the ETCL as digital attachments. The ETCL also has a regular UU webpage containing various 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 ETCL 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 ETCL 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 ETCL be completed.

2.5.2 Standard UiL OTS research

Research which on initial screening in the ETCL 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 UiL OTS (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 UiL OTS research by the entire committee at the next ETCL meeting.

2.5.3 Non-standard UiL OTS research

Research not subject to the WMO which on initial screening in the ETCL web portal is assessed as non-standard UiL OTS research, or which during the accelerated procedure for standard research is assessed not to fit the standard research criteria, will be treated by the ETCL as non-standard UiL OTS research. This means that the study must be discussed by the entire committee at the next ETCL 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 UiL OTS research (see Appendix B for help evaluating this) the researcher should take this period into account for his or her planning.

If the ETCL cannot come to a consensus 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* ETCL 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 *up to the researcher* to submit the intended study in good time; the ETCL is not responsible for delays resulting from its assessment procedure and results.

2.6 What are the consequences of an ETCL decision?

The ETCL has established its assessment policy in consultation with the UiL OTS management, and its decisions on the acceptability of studies are binding to UiL OTS researchers.

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 ETCL 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 ETCL has the final word on the acceptability of UiL OTS research. Only if the researcher with final responsibility believes that a rejection by the ETCL is due to *procedural mistakes* in the evaluation trajectory can a formal objection be submitted to the director of the UiL OTS.

2.7 Who sits on the ETCL and when does the committee meet?

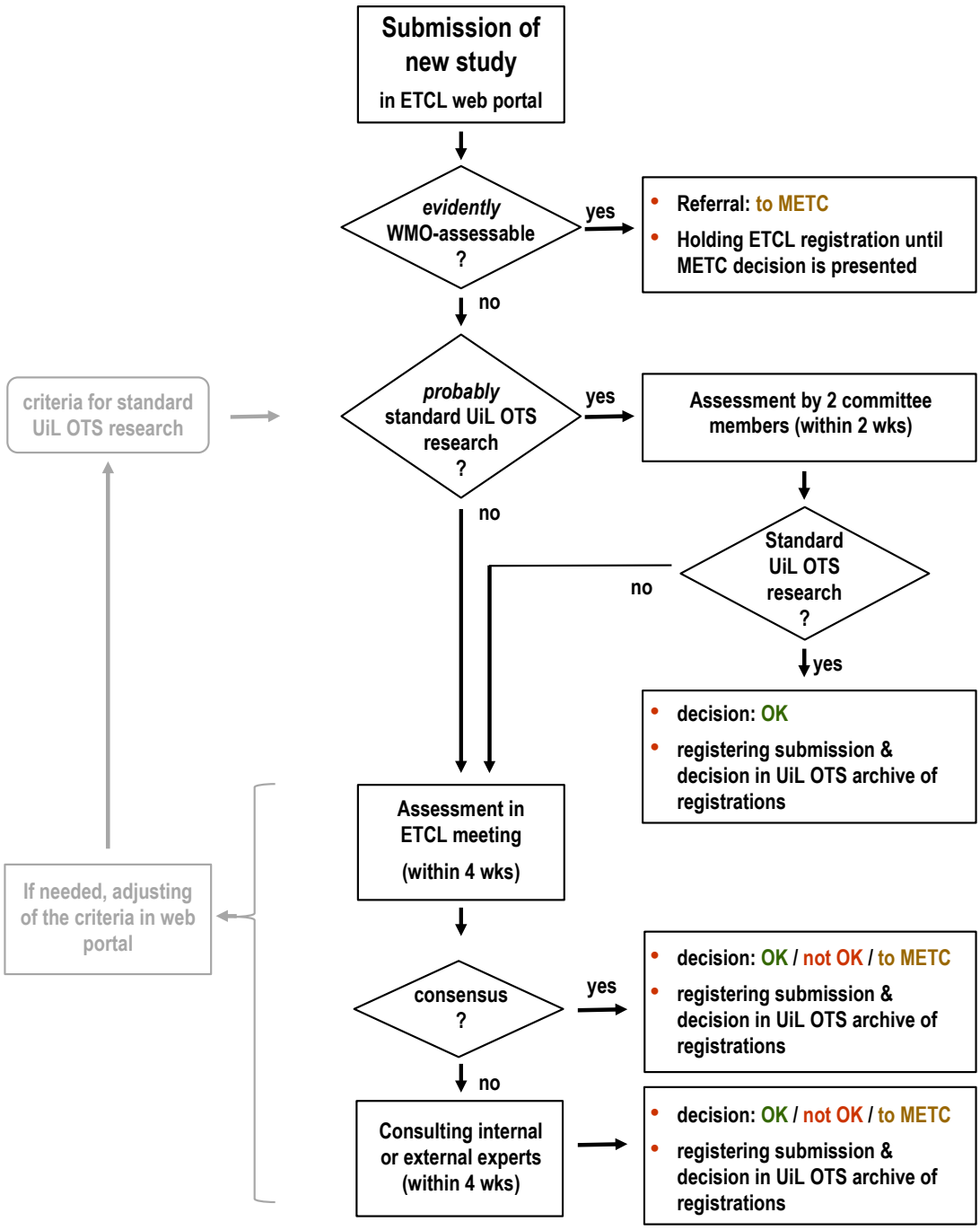
The ETCL consists of five members, each appointed by the director of the UiL OTS for a period of three years. The aim is for the members of the committee to bring together sufficient expertise relating to the diverse kinds of ethical issues which may arise in UiL OTS research. The current composition of the committee can be found on the website of the ETCL.

The ETCL meets on dates appointed in advance, and if necessary also on an ad hoc basis (for the meeting dates see <link ETCL website>). During meetings all applications which have been submitted are discussed. The ETCL'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 ETCL).

The ETCL provides ethical assessment by a minimum quorum of *independent* UiL OTS 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 ETCL meeting will be temporarily transferred to a committee member not involved in the research discussed.

2.8 Flowchart of the regular ETCL assessment procedure

ETCL procedure for new studies
concept6-EN-090216



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 ETCL 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 ETCL of this *immediately* via the portal; amendment of a study in progress. The ETCL 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 ETCL meeting. For questions as to the necessity of an amendment, applicants can contact the ETCL secretary.

2.9.2 Preliminary assessment of research for a subsidy application

The regular ETCL 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 ETCL assessment is not yet relevant. In this case researchers can request a preliminary assessment from the ETCL, by uploading the relevant part of the application in a separate part of the ETCL 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 ETCL 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 ETCL 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 ETCL study assessment; once studies have acquired funding and been worked out in detail they should still be submitted separately to the ETCL for thorough assessment.

The following three sections contain further information on the three pillars of ETCL 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. 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, for every study carried out under the responsibility of the UiL OTS, the UiL OTS researcher should use an adequate information letter and declaration of consent, *based on the relevant templates available on the ETCL website*, see information letter and declaration of consent, and customised 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 ETCL.

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

3.1 Declarations of consent 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 UiL OTS research:

- competent adults, 16+ years old (DC to be signed by the participant);
- adults 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).[5] 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 centre (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 ETCL website here: information letter and declaration of consent, where there are also some completed examples.

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

3.2 Informed consent procedures in special cases

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

3.2.1 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 UiL OTS information letter and declaration of consent. In a web survey or web experiment the relevant UiL OTS 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).

3.2.2 Observational research

The following applies to observational research:

a. If the research makes use of *publically* 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 ETCL will consider the matter at a meeting.

3.2.3 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 towards assessment of the student.

3.2.4 Research with minors

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

a. If the research takes place within a host institution where the child is not interned (e.g. a school, after-school childcare facility, day-care centre), 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 authorised to decide as to participation in the research without consulting parent(s) or guardian (a point which must be demonstrated to the ETCL), 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 ETCL 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 UiL OTS research, stimuli which conceal the researcher's specific goal and for which the data is not used, is not seen by the ETCL as being an ethically relevant form of misrepresentation.

The ETCL 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 ETCL 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 ETCL 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. Partly for these reasons, the UiL OTS uses standard compensation rates (€10 per hour) for participation in different kinds of research; studies can only diverge from these rates in very exceptional and carefully argued cases.

4. Acceptable burden and negligible risks

A second ingredient of ethically responsible research with participants at the UiL OTS 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, stigmatisation 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 stigmatisation by teachers on the basis of tests. The essence of this question is that participating in an UiL OTS 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 ETCL 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 ETCL 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 ETCL 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 UiL OTS research is free to leave or interrupt 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.[6,7]

Once the UiL OTS 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 study should have had an adequate introduction to the use of equipment. See uilots-

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

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 UiL OTS 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 UiL OTS research and which does not come under the METC is standardised test scores in language development research. Where such tests are properly standardised 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 UiL OTS.

4.5 Insurance

For all UiL OTS 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 UiL OTS researchers can join the insurance policy which the Faculty of Social and Behavioural 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 UiL OTS 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 UiL OTS 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 ETCL provides a systematic procedure by which UiL OTS 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 organised ethical assessment therefore also remains a matter of trust, with the final responsibility remaining where it should be.

Feedback? The ETCL 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, Maartje de Klerk. M.K.A.deKlerk@uu.nl

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

Research at the UiL OTS 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 UiL OTS ETCL is not authorised to approve the study independently. Instead the study should first be submitted to a recognised METC (e.g. that of the UMC Utrecht or of another institution involved in the research).

By law[8] 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 behaviour.

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 (aetiology, pathogenesis, symptoms, diagnosis, prevention, outcome or treatment of disease) …* [and which] *… aims to contribute to medical knowledge.'* If an UiL OTS study does not have the aims described above it is *not* subject to the WMO.

UiL OTS 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 ETCL is sufficient. If your *is* medical, even in part, then section A.2 is relevant.

[8] 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 behaviour'?

Only if an UiL OTS 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 behaviour according to the WMO, but in practice the WMO refers to non-trivially burdensome or risky actions or rules of behaviour, 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 behaviour:

- 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 behaviour.
- Research in experimental and social psychology into falling in love.

Unfortunately application of this second criterion is not simple for the individual UiL OTS 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 UiL OTS 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 ETCL. In the latter case the ETCL 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 ETCL.

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 ETCL* 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 ETCL application. If you do not yet have the approval of a METC you should save the ETCL application (i.e. save the partly filled in form in the web portal) until this approval has been obtained.

Appendix B. Criteria for *non*-standard UiL OTS research

The ETCL aims to assess studies as quickly and efficiently as possible, and therefore works with a distinction between standard and non-standard UiL OTS research (see section 2.5). The ETCL 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 differs from the standard UiL OTS regulations.
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).
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 ETCL 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 ETCL operates relatively conservatively (i.e. relatively many files will be discussed in committee meetings). *Always consult the* news *page on the ETCL website when planning your application and your research!*

The ETCL 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 optimised on the basis of progressive insig