Faculty of Behavioural Sciences
Dean's Office

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Protocol for assessing the ethical permissibility of proposed research by the Faculty of Behavioural Sciences at the University of Twente

Established on 2 June 2010 by the
Dean of the Faculty of Behavioural Sciences

Both a Dutch and an English version of this protocol are available. The Dutch version (ref. BFD-GW/2010-174b/pc) exceeds the interpretation of this English version.

Table of contents

1. Principles and background: the Ethics Committee (EC) of the Faculty of Behavioural Sciences (GW) and the responsibilities of the department chairs and researchers

1. This protocol addresses the research-associated ethical issues at the Faculty of Behavioural Sciences.
2. It is for this purpose that the Ethics Committee (EC) of the Faculty of Behavioural Sciences at the University of Twente has been established by the Dean of the Faculty of Behavioural Sciences.
3. The EC consists of a chairperson, a secretary and one member from each department that carries out ethically relevant research. The chairperson and the secretary are appointed by the Dean, as are the members after nomination by the department chair of the department concerned. The Dean can add advisory members to the committee. The EC meets twice a year and as often as required on an ad-hoc basis so that the progress of the research is disrupted as little as possible. The chairperson oversees the running of the EC.
4. The tasks of the EC are to formulate and update the policy of the EC in detail, to approve the so-called standard descriptions of research (the initial editing and subsequent modifications), and **to assess the ethical permissibility** of proposed research projects submitted to the EC which have not been processed according to the so-called fast-track procedure. In this protocol, the concept of proposed research also includes proposed research projects.
5. Based on the so-called fast-track procedure (see below), the EC member of the department is also authorized to make a positive assessment of the ethical permissibility of the proposed research of the department in prescribed cases.
6. The department chair and principal researchers are only authorized by the Dean to engage in research in the department, or have research carried out in the department by a staff member or members of the department, for which a positive assessment of the ethical permissibility of the proposed research has been made by the EC or, in cases referred to hereinafter, by the relevant EC member of the department or, in cases where the EC or EC member is not authorized, a positive assessment has been made by a recognized Medical Ethics Committee. Research for which the EC or the EC member withdraws the positive assessment at a later date must be terminated immediately.
7. All proposed research which involves the use of **subjects** and which is carried out by the Faculty of Behavioural Sciences must be **submitted** to the Ethics Committee or the relevant EC member for an assessment of the ethical permissibility **before** conducting the study. Research which makes use of existing data, such as meta-analyses, does not need to be tested by the EC. On publication, however, it is important to comply with the rules and regulations concerning anonymity and suchlike.

   This protocol applies to research carried out both by ordinary/normal staff members and persons affiliated to a department in connection with the research (including guests, distinguished professors, seconded staff) as well as by doctoral candidates, postdocs and students. Research that is carried out either entirely or in part on the premises of the faculty must in any event be submitted for assessment. There is always a researcher in the employ of the Faculty of Behavioural Sciences who bears primary responsibility for the research. Should the research be carried out by a student or intern or hired worker, responsibility will be borne by a staff member of the department. Researchers, who are also employed by another institute, should submit their research to the institute to which the principal researcher is primarily affiliated, and in any case, to the institute where the research is to be carried out. Research which is conducted elsewhere (for instance at a school, company or institute) on behalf of a faculty member of staff should also be submitted to the EC or the EC member using the so-called fast-track procedure. Proposed research *involving subjects within the framework of education* should also be submitted in good time.
8. This protocol sets out the rules and conditions that apply to research which has (previously) been found to be ethically permissible and for which the EC may decide to make a positive

assessment. These decisions are binding. The department chair may submit a motivated request to the Dean for a review of the decision that has been made by the EC. The research may not be carried out before the EC has deemed the proposed research to be ethically permissible or before the Dean has reviewed the decision and found the proposed research to be permissible after all.

9. Research, which has not been given a positive assessment regarding ethical permissibility, does not fall under the responsibility of the faculty and the Dean. In this case, it would be carried out at the own risk and responsibility of the researcher who would then be held personally liable (inter alia sections 1.8 and 1.17 of the Collective Labour Agreement Dutch Universities (CAO NU).
   In the light of social developments, experiences in the field of research and insights developed by the EC, rules and conditions may change and the permissibility of the research can thereby come under discussion at any time. Barring a request submitted to the Dean for review, the EC has the final word concerning the ethical permissibility of research, except in cases where a Medical Ethics Committee (MEC) is authorized. The EC may, under exceptional circumstances or for special reasons, also terminate ongoing research.
10. The purpose of this procedure and the EC is to streamline the process of assessing the ethical permissibility of the proposed research as much as possible so that the proposed research can proceed with as little hindrance as possible, the lines are kept short and the procedures kept clear. Unnecessary administration workloads for researchers are avoided as much as possible. Thus, a number of forms of so-called **'standard' research** have been defined for practically every individual department. These forms and respective descriptions may be supplemented and modified along the way. Standard research refers to research which has been conducted within the faculty for many years and which is often also conducted internationally on a regular basis whereby the differences between the various studies do not have any consequences for resulting ethical considerations. For instance, research in which the stimulus material, type of questionnaire or type of experiment only marginally differs from studies that were previously deemed acceptable.

2. Procedure to apply for an assessment by the Ethics Committee of the ethical permissibility of the proposed research

2.1 Procedure

If the **research *falls entirely* within** a **standard** form as indicated in the previous chapter, and if, as judged by the EC member of the relevant department, the research corresponds with research previously carried out and approved, then a ***fast-track procedure*** will apply***.*** The EC member of the department is authorized to assess the ethical permissibility of the proposed research. The EC member bases his/her assessment on the information which is evident from the submitted **checklist** (see Chapter 3), the submitted *information brochure* and the *informed consent forms*. The EC member checks the data and can then make either a positive or a negative decision (after obtaining additional information if need be) about whether the proposed research is ethically permissible. The EC member informs the principal researcher and the secretary of his/her decision. Research for which a EC member is him-/herself responsible shall be submitted by the EC member to a EC member of another department. If no EC member from the department is available or appointed, then the request shall be submitted to an available EC member via the secretary. The EC member informs the EC of his decision via the secretary. The department chair can submit a request for review to the Dean in the event of a negative decision regarding permissibility.

In all other cases, the proposed research should be submitted in detail to the EC via the secretary. The EC member of the department where the research is conducted should subsequently report his/her initial findings to the EC. Also in this case, the checklist should be filled in and the *information brochure* and the *informed consent forms* submitted. These sources are supplemented with information indicating on which points the research differs from standard research, and with all the information that is required to enable the EC to reach a decision about the ethical permissibility. The decision regarding the ethical permissibility is taken by the EC as an entity, except in those cases where an MEC (see Chapter 4) is authorized.

Proposed research which is submitted via the secretary to the EC as an entity (and therefore not a fast-track procedure), is dealt with in the following regular EC meeting, or sooner if there are urgent reasons for doing so. A decision on the ethical permissibility of the proposed research is therefore taken as quickly as possible (unless further information is requested and this information is not provided in good time, in which case the period before a decision is made will be relatively later).

2.2 Essential information in order to assess the ethical permissibility of the proposed research

Department: To assess the ethical permissibility of the proposed research, it is important to know in which department a certain type of research will be carried out. Often, the researchers within that department already have plenty of experience with that type of research. Research that has not yet been carried out by a particular department will more likely need to be scrutinized by the EC. It is therefore necessary to establish in which department the proposed research will be carried out and which department is responsible. This refers to the actual execution of the research; in other words, in which department does the person actually performing the research work or the supervisor of the doctoral candidates or students concerned. The final decision as to which department ought to carry out the research in terms of the ethical permissibility rests with the relevant EC member of the department.

Regarding parts of the research project: A separate assessment request must be submitted for each clearly distinct component of the project. This can also imply that different parts be placed with different departments. The main researcher is in principle at liberty to determine for which parts of the

research a separate request is submitted. A choice can be made to submit a separate request for a) each individual assignment or internship of a student, b) each component of a doctoral research, c) each part which demands a different research method.

Description of the research: Two descriptions of the research will be written up which will:
(1) be used for assessment by the EC or by the EC member concerned (see checklist Chapter 3), and (2) provide information to the subjects and support for the informed consent form. On the basis of this final *information brochure*, subjects should be able to form a clear impression of the burden, risk or discomfort involved in the research. The brochure should also include other conditions and provisions (see *informed consent*) with regard to remuneration, voluntariness, screening, insurances, anonymity etc. An *informed consent form* is drawn up for subjects to sign should they decide to participate in the research after having taken cognisance of the information brochure. In the event of information presented to subjects being misleading owing to the setup and purpose of the research, then supplemental conditions will apply.

Checklist: The **checklist** should be filled in (see Chapter 3) for the benefit of the assessment request. The questions on the checklist should of course be answered truthfully. However, it is also expressly requested that the questions be answered in line with *the spirit* of the text and not so much to the letter. In other words, it is not the intention that a somewhat vague formulation should be interpreted to one's own advantage. In the case of even the slightest doubt, the answer 'uncertain' should always be filled in. This applies especially when answering the question as to whether your research falls within a particular standard category. It is indeed impossible to provide for all possible versions of a particular research and these descriptions are therefore not exhaustive. In terms of this protocol, proposed research is standard research if and when *all* the conditions set out in the description thereof are satisfied. Here too, in the case of even the slightest doubt, the answer 'uncertain' should be filled in.

Applicability of the fast-track procedure: After completing the checklist, it should be apparent whether the proposed research can follow a so-called *fast-track procedure* or whether it should be *submitted to the entire EC*. It may also be apparent that the proposed research falls outside of the jurisdiction of the EC of the Faculty of Behavioural Sciences, in particular because the research falls under the *Wet Medisch Onderzoek (WMO)* [Medical Research Involving Human Subjects Act]. In that case, the research should be assessed by a recognized Medical Ethics Committee, such as that of the Enschede-based Medisch Spectrum Twente (MST).

Fast-track procedure: In the case of a *fast-track procedure*, the principal researcher only needs to send the checklist and the corresponding documents (informed consent, information brochure for subjects) to the EC member of the relevant department and copies to the secretary of the EC. The EC member concerned informs the researcher directly (per email) about the ethical permissibility of the proposed research and sends a copy thereof to the secretary. *Thereafter*, the research may commence. The EC member of the department where one's research is to be conducted may request further information should (s)he find this necessary. In that case, no decision will have yet been made on the ethical permissibility.

3. Checklist for the principal researcher when submitting a request to the EC or the EC member for an assessment of the ethical permissibility of the proposed research

3.1 General

When answering the questions, it is advisable to consult the chapter on standardized research because the answers will be considered with this in mind.

1. Title of the project:
2. Principal researcher (with doctoral research also a professor):
3. Researchers/research assistants (doctoral candidates, students etc. where known):
4. Department responsible for the research:
5. Location where research will be conducted:
6. Short description of the project (about 100 words):
7. Expected duration of the project and research period:
8. Number of experimental subjects:
9. EC member of the department (if available):

3.2 Questions about fulfilled general requirements and conditions

1. Has this research or similar research by the department been previously submitted to the EC?
   ☐ Yes,
   ☐ No
   If yes, what was the number allocated to it by the EC?
   Explanatory notes:

2. Under which category does the research fall with regard to the consideration of Medical / Not medical? (Also see Chapter 4.)
   ☐ Category D
   ☐ Category A
   ☐ Category B
   ☐ Category C
   ☐ Uncertain, explain why
   Explanatory notes:

3. Are adult, competent subjects selected?
   ☐ Yes, indicate in which of the ways named in the general requirements and conditions this is so
   ☐ No, explain
   ☐ Uncertain, explain why
   Explanatory notes:

4. Are the subjects completely free to participate in the research, and to withdraw from participation whenever they wish and for whatever reason?
   ☐ Yes
   ☐ No, explain why not
   ☐ Uncertain, explain why
   Explanatory notes:

5. In the event that it may be necessary to screen experimental subjects in order to reduce the risks of adverse effects of the research: Will the subjects be screened?
   ☐ Screening is not necessary, explain why not
   ☐ Yes, explain how
   ☐ No, explain why not
   ☐ Uncertain, explain why
   Explanatory notes:

6. Does the method used allow for the possibility of making an accidental diagnostic finding which the experimental subject should be informed about? (See general conditions.)
   ☐ No, the method does not allow for this possibility
   ☐ Yes, and the subject has given signed assent for the method to be used
   ☐ Yes, but the subject has not given signed assent for the method to be used
   ☐ Uncertain, explain why
   Explanatory notes:

7. Are subjects briefed before participation and do they sign an informed consent beforehand in accordance with the general conditions?
   ☐ Yes, attach the information brochure and the form to be signed
   ☐ No, explain why not
   ☐ Uncertain, explain why
   Explanatory notes:

8. Are the requirements with regard to anonymity and privacy satisfied as stipulated in § 5.2.7?
   ☐ Yes
   ☐ No, explain why not
   ☐ Uncertain, explain why
   Explanatory notes:

9. If any deception should take place, does the procedure comply with the general terms and conditions (no deception regarding risks, accurate debriefing)?
   ☐ No deception takes place
   ☐ The deception which takes place complies fully with the conditions (explain)
   ☐ The deception which takes place does not comply with the conditions (explain)
   If deception does take place, attach the method of debriefing
   Explanatory notes:

10. Is it possible that after the recruitment of experimental subjects, a substantial number will withdraw from participating because, for one reason or another, the research is unpleasant?
    ☐ No
    ☐ Yes, that is possible
    If yes, then attach the recruitment text paying close attention to what is stated about this in the protocol.
    Explanatory notes:

3.3 Questions regarding specific types of standard research

Answer the following questions based on the department to which the research belongs.

11. Does the research fall ***entirely*** within one of the descriptions of standard research as set out in the described standard research of the department?
    ☐ Yes, go to question 12
    ☐ No, go to question 13
    ☐ Uncertain, explain what about, and go to question 13
    Explanatory notes:

12. If yes, what type of research is it? Give a more detailed specification of parts of the research which are not mentioned by name in this description (for example: What precisely are the stimuli? Or: What precisely is the task?)

13. If no, or if uncertain, give as complete a description as possible of the research. Refer where appropriate to the standard descriptions and indicate the differences with your research. In any case, all possible relevant data for an ethical consideration should be provided.

4. Assessment of the ethical permissibility of proposed research by the Medical Ethics Committee (MEC) or Ethics Committee (CE)

4.1 Introduction

When should the research at the Faculty of Behavioural Sciences be tested by a nationally recognized Medical Ethics Committee (MEC), and when does assessment by the local Ethics Committee (EC) of the Faculty of Behavioural Sciences suffice? Interpretation of the WMO [Medical Research (Human Subjects) Act, 2006] with regard to this question is not always very clear. Following the example of other universities (such as University of Amsterdam, Maastricht University and Leiden University), we have decided to formulate our own interpretation of the WMO (see below).

4.2 Primary Selection Criteria

Research must in any case be submitted to an MEC when:

1. A hospital is involved in the research (according to section 7.5 WMO), that is to say if **one or more** of the following conditions are met:
   a. A hospital is involved in the research as a client or as a provider/executioner.
   b. The research takes place within the walls of the hospital and, in view of the nature of the research, should not normally take place outside of the hospital walls.
   c. Participating in the research are patients/clients of the hospital (in that capacity).
2. The research is **medical** by nature and involves a **non-negligible risk** for the subject (see section 1.1 heading sub b j° section 2 WMO; see also MvT [Explanatory Memorandum] & Ministerie van VWS (2000) [Ministry of Health, Welfare and Sport]).
3. The research is **medical** by nature and involves a **negligible risk** for the subject.

For non-medical research, the main criterion with regard to the ethical permissibility is the risk to the subject. In the case of psychological research, the EC is capable of forming an opinion. If medical equipment is used in the research, then the EC may seek advice from an MEC regarding the risks connected with such equipment.
Agreements are prepared with the MEC of the MST concerning their service provision.

4.3 Secondary selection criterion: Nature of the Research: Medical or Non-Medical

Research is medical by nature when:

1. The question is directed at etiology (pathogenesis and course), diagnostics and/or treatment of somatic illnesses which can only be treated by an authorized medical specialist; or
2. The question is directed at the effect of medicines which may only be prescribed by an authorized medical specialist; or
3. The research requires carrying out medical procedures. (In accordance with the Wet Beroepen in de Individuele Gezondheidszorg 1996 [the Individual Healthcare Professions Act], the following procedures are reserved for medical practitioners: surgery, obstetrics, endoscopies, catheterizations, injections, punctures, anaesthetization, the use of radioactive materials and ionizing radiation, cardioversion, defibrillation, electroconvulsive therapy, lithotripsy, artificial fertilization); or
4. The research requires administering repetitive transcranial magnetic stimulation (rTMS); or
5. The research requires administering medicines or collecting body tissue or fluids (with the exception of saliva, breath, sweat or urine samples); or

6. The research involves administering non-medicinal substances (not on prescription from an authorized doctor as medicine) such as (extracts from) artificial fragrances and flavourings or psychoactive substances **other than**
   a. Substances which are currently in normal social use or found in a normal diet
   b. Substances which are freely and legally available on the consumer market
   c. Substances which do not carry any warnings (either on the packaging or instruction leaflet) regarding health damaging effects or side-effects (other than for instance alcohol and caffeine) to subjects who would normally use these substances in a social context and in generally socially acceptable doses; or
7. The research involves administering non-medicinal safe substances as named above but in doses which are not currently in social use or found in a normal diet or which are not generally socially acceptable; or
8. For the sake of the research, subjects must (temporarily) stop taking their medication; or
9. The research otherwise falls under the authorization of a medical specialist and therefore must necessarily take place under the supervision or partial supervision of an authorized medical specialist.

4.4 Secondary selection criterion: Degree of Risk, negligible or non-negligible

In the text of the Medical Research Act (*WMO*), risks (and formal objection) are not further defined. In operational terms, research in this protocol is defined as risky if, as a direct result of the research (whether or not as a result of deception, and whether or not as a result of potentially emotion-inducing or stress-inducing stimuli (in the broadest sense of the word)), there is a more than negligible chance, either for the subject or third parties, of:

1. Violation of privacy,
2. Addiction (physical or mental) to an activity carried out in the research (e.g. gambling) or to a product administered in the research,
3. Psychological disorder, psychological distress or psychological trauma, either of a permanent nature, or otherwise of a nature requiring therapeutic or psychiatric treatment or prescribed medication,
4. Physical injury, allergic reaction, discomfort or pain, either of a permanent nature, or otherwise of a nature requiring medical treatment or prescribed medication.

4.5 Nature of the Research & Degree of Risk: Assessment Table

The selection criteria named in 4.2 and further explained in 4.3 yields the following table:

Secondary Selection criteria 4.3		Degree of risk	
		Non-negligible	Negligible
Nature of the Research	Medical	Type A for assessment by **MEC**	Type B for assessment by **MEC**
	Non-medical	Type C for assessment by **EC** and where appropriate in consultation with **MEC**	Type D for assessment by **EC**

4.6 Tertiary selection criterion: legal incapability and persons younger than 18 years old

According to section 4 of the WMO, it is forbidden to conduct scientific research on subjects who are younger than 18 years of age (or persons who cannot be deemed capable of giving informed consent). The basic principle of the WMO for this category of subjects (legally incompetent/incapable) is ‘no, unless’.

The exception named in section 4 includes:

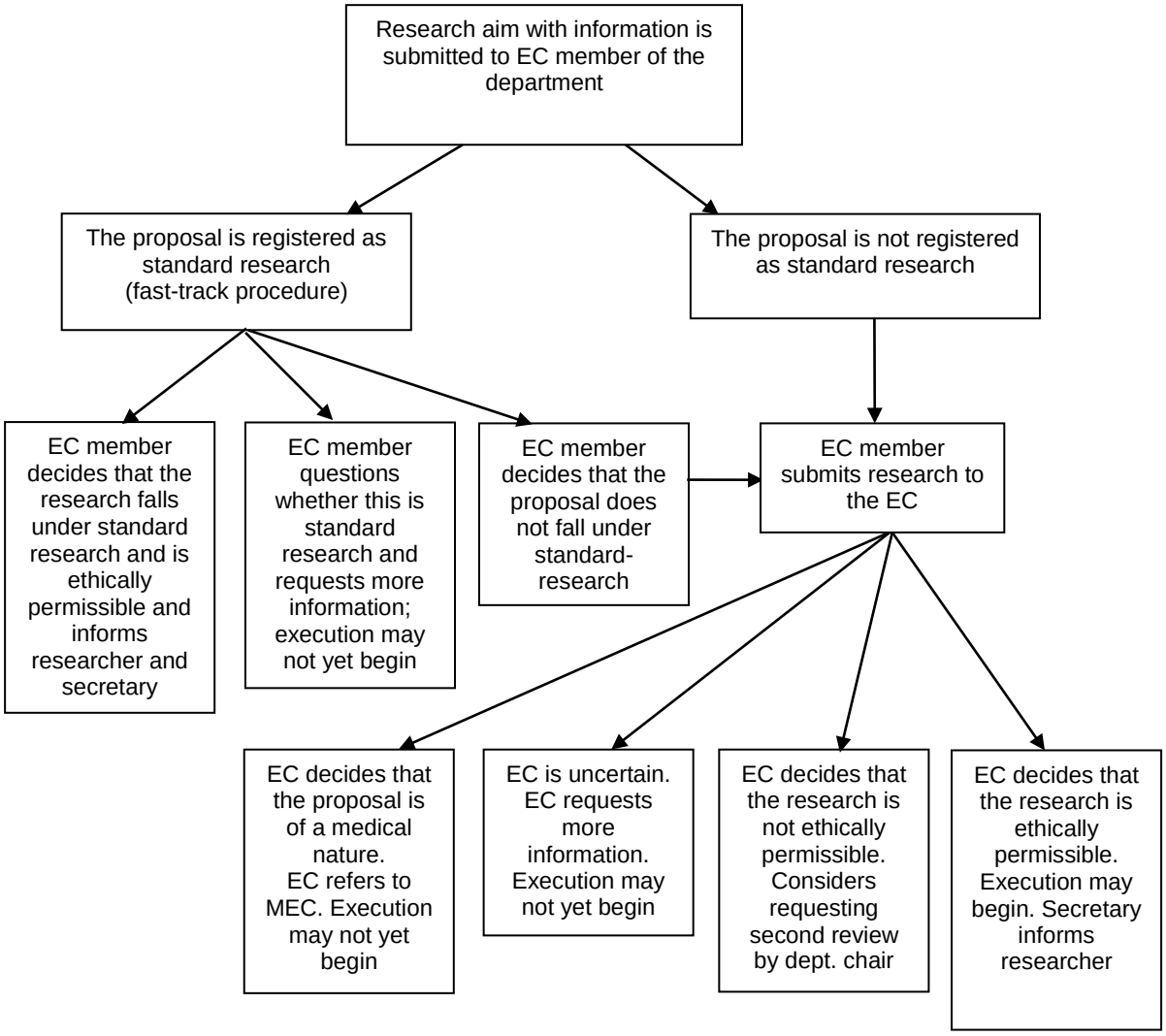
1. Research which may be beneficial to the subjects themselves; and
2. Research that cannot be conducted other than with the participation of subjects from the category to which the subject belongs and for whom the risks are negligible and the formal objections minimal.

Research involving legally incapable subjects requires an ethical assessment by an MEC.
Research involving subjects who by virtue of age are legally incapable may be assessed by the EC in consultation with an MEC where appropriate or by the EC alone.

4.7 Summary of the rules for the assessment of the ethical permissibility of research by the Medical Ethics Committee (MEC) or the Ethics Committee (EC)

Medical research is always assessed by an MEC. Non-medical research is initially assessed on ethical permissibility by the EC. In particular, assessing the risk or discomfort that the subject will be subjected to plays a primary role. If necessary or desirable, the EC may seek advice in its deliberations regarding any possible risk to the subjects. Should this risk be of a medical nature (that is to say it concerns health), the EC shall turn to a recognized MEC. In other cases, advice can be sought from another specialist (lawyer, ethicist).
The use of medical and paramedical equipment (for example, MRI scanners, EEG, TMS, blood pressure monitors or other physiological measurement devices), but also other procedures carried out on the body (for example, exposure to extreme conditions) or which elicit or require physical reactions (for example effort) can involve risks for certain groups of people. With the exception of the specified procedures (fast-track procedure with regard to ‘standard’ research), an assessment of ethical permissibility must always be submitted to the EC for the use of such equipment or such procedures before establishing that this will not pose any risk to the subject.
Research involving legally incapable subjects is always tested on the exception clause named in section 4 of the WMO (see 4.6 above).

4.8 Flowchart for assessment of the ethical permissibility of the proposed research



5. Standardized research within the Faculty of Behavioural Sciences

5.1 Introduction

Within the context of this protocol, proposed research can fall under so-called standardized research per department of the Faculty of Behavioural Sciences. In this case, the proposed research is submitted for a decision regarding ethical permissibility to the EC member of the relevant department, with a copy thereof to the secretary of the EC. This EC member makes a decision on the ethical permissibility. This 'standardization' means that a decision about the ethical permissibility of commonly occurring proposed research can be made relatively quickly and carefully.
In the context of this protocol, research is only standardized if it fulfils ***all*** of the general requirements and conditions of the standard types of research for the relevant department, or two types of requirements.
In the context of this protocol, only proposed research which falls entirely within the hereinafter named general requirements and conditions and the hereinafter named specific types, differentiated per department, is 'standard research'. All the requirements and conditions listed for that type of research must be fulfilled *and* the research must be conducted by a researcher from the relevant department.
If no specific types of research have (as yet) been identified for a department and if there are no completely similar types present in other departments, then the so-called fast-track procedure is not applicable.

5.2 Standardized research: general requirements and conditions which should be fulfilled

5.2.1 Authorization EC: assessment of ethical permissibility by EC or by MEC

First of all, it must be established whether the research ought to be assessed by a recognized Medical Ethics Committee (MEC). Should this be the case, the EC of the Faculty of Behavioural Sciences is not authorized to make a decision about the ethical permissibility of the research. The proposed research is submitted to a recognized MEC in this case (for instance from the MST or from another institute which is involved in the research). The hereinafter listed selection criteria for determining whether research should be assessed by the EC or else by an MEC, as well as a flowchart to establish this quickly, can be found in chapter 4. Research which according to this selection procedure falls into category D, satisfies the requirement for standardized research. Research in categories A, B or C is never standard research. Research in categories A or B (medical research) should always be submitted to a recognized MEC. Research in category C should be submitted to the EC which, when appropriate, will seek advice from an MEC with regards to the medical risk of that research.

5.2.2 Selection of adult, competent subjects

A subject is a healthy, adult (18 years or older) and mentally competent volunteer, who voluntarily participates in a trial and receives a modest remuneration in return. Subjects are selected in one of the following manners:

a) B1 and B2 students in the Psychology and Communication study programmes spend 15 hours participating in research in order to gain experience in conducting research. Every year, more than 100 research studies are on offer and subjects are at liberty to register in the pool of studies offered (via www.psy.utwente.nl/bachelor_psy/proefpersonensysteem/ and www.cw.utwente.nl/bachelor/handleidingen/proefpersonensysteem/ respectively. Apart from the actual participation, the didactic aspect also lies in providing explanatory notes afterwards about what the research has yielded and precisely how it was designed and conducted. The research leader undertakes to inform the students who are participating via this system to this effect.

b) A subject is recruited through an advertisement in the newspaper, the UT-Nieuws or by a poster in one of the Campus buildings of the UT or other (educational) institutions. Subjects are also

recruited by companies or organizations with access to groups which are relevant to the research such as 'managers' or 'cultural minorities'. Participation is remunerated. The standard remuneration is € 6 per hour, but the remuneration may be higher depending on the discomfort connected with the research. The standard remuneration is established annually. It is however not allowed to exceed certain maxima with the purpose of enticing subjects to participate in research which they would otherwise not be very inclined to participate in. As an example, for filling in questionnaires or participating in research which falls under the heading of 'behavioural tasks' (whether alone or in a group), no more than € 10 per hour may be paid. If physiological measurements are taken which involve a very limited degree of discomfort (for example heartbeat, EEG, fMRI), a maximum of € 15 per hour may be paid. For research which involves more discomfort (but which still only carries a negligible risk, for example cold stress), a maximum of € 20 per hour may be paid. For research which entails making use of Transcranial Magnetic Stimulation (TMS), € 0.10 per pulse is paid up to a maximum of 300 pulses per day. Sometimes, subjects are not remunerated individually but the remuneration is in the form of a lecture for the company or the organization where the subjects were recruited. Or it may be a combination of credits procured via the subjects system plus an amount of money. The amounts listed here were applicable in 2010.

c) A subject is recruited through an advertisement in the newspaper, UT-Nieuws or by a poster in one of the Campus buildings of the UT, the Saxion Universities of Applied Sciences, Edith Stein University of Applied Sciences and the ROC in Twente. The persons sought are those who can be identified by a certain characteristic or experience which does occur regularly (2-10% incidence) but which does not fall into the 'pathological' category. (When subjects meet the DSM-IV criteria for a particular disorder, this research falls under medical research and must therefore be submitted to an MEC). Suitable subjects could be trauma victims or people with arachnophobia (fear of spiders), social anxiety, dyslexia, ADHD or other more or less mild conditions. Participation is remunerated with an amount which is in relation to the discomfort involved in the research (varying from € 10 to € 15 per hour).

d) The researcher approaches an institution (school, healthcare institution, company, etc.) regarding participation in the research whereby the heads of these institutions in their turn approach the residents/members/students about participation. This applies always to adult persons. (For minors or legally incompetent subjects, see under the relevant department which makes use of these subjects. Participants sign the *informed consent* individually, although it might be on the same form. When participation takes place in an institution (e.g. school, healthcare centre) or at the parents' home (on a voluntary basis), there is normally speaking no financial remuneration, although there is in this case usually a small gift for the participant or for the host institution.

e) Subjects are individually interesting for a particular reason, for instance because they have participated in an earlier research or because certain data has already been collected from them. On the basis of this, a subject can be approached individually to participate in a (follow-up) research. Example: a subject has previously participated in an fMRI experiment during which an MRI scan was made. This scan has been further processed to produce a segmented brain image for example. Making such an image segmentation costs a great deal of time and making an MRI scan costs a lot of money (for a good scan, about 3 shorter MRI scans lasting 10 minutes each are necessary). This is why it is handy if such a subject participates in more experiments and why (s)he may be asked to participate in a follow-up research.

5.2.3 Voluntariness of participation

Regardless of the selection method used, each subject is free at any moment and for any reasons whatsoever to leave or break off the research. Also, after the research has ended, but within 24 hours, the subject might decide that his/her data may not be used in the research after all. Persons who have been approached either individually or as part of a group may not be put under pressure (including

peer pressure) to participate, nor may any remuneration be promised which is higher than that stipulated above.

5.2.4 Screening of subjects

Should the research so require, subjects will be screened for common or less common disabilities. This could include eye examinations or other visual tests in the case of research on visual perception or questionnaires about either neurological or psychiatric disorders in the case of EEG studies or claustrophobia in the case of fMRI research. In the case of TMS and fMRI research, special screening procedures are always required in order to ensure a negligible level of risk in these experiments. Furthermore, certain inclusion or exclusion criteria can be employed such as a particular age range, a particular range in IQ-score or other psychometric test score, whether or not for matching with other subjects.

5.2.5 Accidental discoveries

Some methods of research can lead to accidental discoveries which may be of vital importance to the subject, such as an irregular heartbeat on an ECG, an abnormal EEG (epilepsy), or an abnormality on an fMRI. If there is any chance of this occurring, a clause should be included in the informed consent which makes provision for the procedure to be followed in this case. In such trials, the subject should provide the name and location of his/her general practitioner, or the full address of the GP's surgery or group practice to be notified in the event of a discovery that may be of vital importance to the subject. Should the subject not have a general practitioner, then (s)he should agree to a student medical service doctor or, more commonly, a company doctor being notified. The subject must agree to this procedure and acknowledge this by signing a separate clause on the informed consent form. Should the potential subject not sign, then said person may not participate in the research.

5.2.6 Informed consent and minimum content of the Information brochure

Informed consent means that the subject agrees (/consents) to the research being carried out, and that (s)he gives this written agreement on the basis of correct and full information with respect to the expected procedures, discomfort, risk, duration, purpose etc. Presenting the subject with an informed consent document is mandatory. For subjects who are incapable of giving informed consent, such as children, legal representatives will be asked to give their consent.

Prior to conducting the research and during the recruitment of subjects, the researcher should inform the subjects about what they can expect during the research. On the basis of this information, the subject is asked explicitly for permission to use the data obtained from him/her for research. After taking cognizance of the information brochure relating to the research, and prior to participation in the research, the subject (or his/her legal representative) signs an *informed consent form*. The information brochure and informed consent form can be two separate documents or combined in a single document. For standard examples of information brochures and informed consent forms see Chapter 6.

5.2.6.1 Minimum content of the information brochure

The ***information brochure*** should contain at least the following:

a. The name, the address, telephone number and email address of the research leader.
b. The name, address, telephone number and email address of a person other than the research leader who is not directly involved in the research, and whom the subject can contact with queries, complaints or comments about the research. In principle, this is the secretary of the CE.
c. The research procedure, activities to be carried out etc. On the basis of this information, the subject should be able to make a reasonable estimate of the expected discomfort, duration and possible risks (even if these are negligible) involved in the research. This description should be written in clearly understandable language, free of jargon or unusual abbreviations.
d. All factors which could possibly influence the willingness to participate, such as risks, discomfort or adverse effects.

e. The remuneration for participation in the research, and the conditions governing payment. When professional services (such as treatment or education) are offered as remuneration for participation in the research, the researcher must make clear to the subject what the nature of the services are as well as the risks, obligations and limitations involved in these services.
f. The categories of persons who are advised not to participate in the research due to an increased level of risk or discomfort to said persons. This would include persons with claustrophobia in fMRI experiments, people with the tendency to faint in emotional-stress experiments, pregnant women in research involving substances like alcohol, etc. (This is apart from the screening which is required for some categories of research).
g. The purpose of the research. If the purpose of the research cannot be revealed beforehand due to the nature of the research question, then an explanation must always follow as quickly as possible after the research has ended, with a debriefing which explores the possible adverse effects of the deception. The researcher may never mislead the subject about important aspects of the research which may have an influence on willingness to participate such as risks, discomfort or adverse effects.
h. A declaration to the effect that the anonymity of subjects participating in the research will be guaranteed and that data will not be disclosed to third parties without the permission of the subject.
i. A paragraph which states that participation remains at all times voluntary and that without giving any reasons, subjects may refuse to participate in the research, and that they may also end their participation at any time and that they may also refuse afterwards (within 24 hours) to allow their data to be used for the research. All of this may not at any time have any adverse consequences for the subject, for his/her course results etcetera. Any payments 'earned' up until this point will be paid out (in proportion to the duration of participation).
j. If there is a possibility of accidental discoveries, the procedure to be followed should be stated here. The subject must explicitly agree to this procedure and acknowledge this with an extra signature on the informed consent form.
k. The debriefing procedure at the end of the research (if this is provided for) and which persons will be involved in this as well as their position/function.

5.2.6.2 Content of the informed consent form

On the informed consent form, to be signed by both the researcher and subject, it is stated that the subject has taken cognizance of the contents of the information brochure and fully understands the information. (If the information brochure is separate from the form to be signed, there must be an explicit reference on the form to the relevant information brochure.) Should there be any additional provisions (screening, accidental discoveries, debriefing), the subject must sign separately for these procedures and also provide the necessary information (e.g. name and address of general practitioner). The form also contains all the contact addresses as they are listed in the information brochure. The subject receives a copy of the form, and if so desired, a copy of the information brochure to take home.

An exception to the abovementioned informed consent procedure can be made in research where a questionnaire is presented without the research leader and subject actually meeting, such as when a questionnaire is sent by post and filled in at home, or when it is presented via a website. In that case, the researcher provides the abovementioned information via an accompanying letter or via the website and adds a declaration to the effect that by participating in the questionnaire, permission is implicitly given (or there is a box to tick). Also in this case, the subject is free at any moment to quit the questionnaire.

5.2.7 Anonymity

Data obtained from research is not disclosed to third parties (published or disclosed in colloquia or in internal consultations) in any way that would make it possible to link the results or other findings with a particular subject. An exception to this is stated in 5.2.6.1 under f, whereby results from an earlier research are put forward as a selection criterion for subjects. In such a case, the data to be exchanged are scrambled as much as possible and are in no way disclosed to any persons other than

those involved in conducting the studies. Of course, data in such cases are made anonymous after collection; the same applies to publication etc, which in such cases is always anonymous.
In commonly occurring cases, it can be useful to use the results of one particular subject for didactic purposes (education, congress presentations, scientific documentary, and the like). If the subject thereby runs the risk of his/her anonymity being violated, as in the case of photographs, video or audio recordings, but perhaps also 3D image renderings of fMRI data, then explicit permission for this should be requested after the research has terminated. The use of such data is allowed only for those purposes for which the subject (or his/her authorized representative) has granted separate written (and undersigned) permission to the researcher. The data in which subjects are identifiable are carefully stored and are destroyed whenever the interest of the research allows for this. In general, the researcher must operate in accordance with privacy legislation.

5.2.8 Deception and debriefing

Certain forms of deception of subjects are allowed. After all, sometimes it is necessary that a subject does not have an accurate idea of the precise purpose or procedure of the experiment. Deception is defined as providing inaccurate or incomplete information to the subject. In the following chapter about the different types of standard research, there is a listing of the forms of deception which are normally allowed for each department.

In general, the following applies:

a. Deception is not allowed concerning information about the possible risks which are linked to participation.
b. Deception is only allowed if there is no possibility of answering the research question without deception.
c. Following deception is always a complete debriefing of the subject about the way in which (s)he has been misled. If there is reason to expect temporary negative effects from a deception, then this debriefing must take place immediately after the end of the experiment (for instance if false negative feedback was given on intelligence scores, then debriefing takes place immediately). The debriefing is carried out in such a way as to reasonably expect that it would eliminate the temporary negative effects on for instance self-image and mood. If no temporary negative effects are anticipated, the debriefing may also take place at a later stage, but it must be within one month after the end of the experiment at the latest.

5.2.9 Recruitment of subjects

When recruiting subjects, it is not necessary to mention all of the information about the research to the same extent as is required in the information brochure. However, it is necessary during the recruitment that the following is made clear:

a. Whether there are any unpleasant procedures of which it is already certain beforehand that they will prevent a substantial number of subjects from participating. For instance, procedures which evoke physical pain or procedures which last an extremely long time, etc. It should not be the case that the subject does not hear about this until after (s)he has applied to participate in the research. Then there is a risk that a small number would still not ‘dare’ to refuse. Moreover, subjects are entitled to some remuneration after such a withdrawal, which means there is a risk that many unnecessary payments would have to made for the research.
b. Whether there are groups of subjects who are excluded from the research or who are advised not to participate because they would run a higher risk than normal by participating. For example, people with metal clips and the like for fMRI or TMS, or pregnant women for experiments with alcohol, etc.
c. Whether material is used which for certain groups of people is offensive or inappropriate, for instance on grounds of religious belief. Examples include racial or explicit sexual photographs or films, use of alcohol and the like.

5.3 Specific types of standard research per department

In the context of this protocol, only proposed research which falls entirely within the hereinafter named general requirements and conditions and the hereinafter named specific types per department can be denoted as 'standard research'. All the requirements and conditions listed for that type of research must be satisfied *and* the research must be conducted by a researcher from the relevant department.

5.3.1 Department of Cognitive Psychology and Ergonomics (CPE)

Explanatory notes about fulfilled general requirements and conditions

Authorization CE: assessment of ethical permissibility by EC or by MEC
Research conducted by the CPE generally makes use of healthy, adult and competent subjects who participate on a voluntary basis (often for the sake of study credits) or for a minimal financial remuneration. In a few cases, students are selected on the basis of mild conditions such as dyslexia, ADHD, or on the basis of other criteria (e.g. synesthesia or number of years' musical experience). In this case, recruitment takes place by means of posters or announcements at the beginning of large-scale lectures, and in a few instances, by approaching study advisors who have information about relevant data. In this last case, enquiries are only made indirectly (via the study advisor) concerning interest in participation, after which the students can themselves contact the relevant researcher. Research focuses on basic cognitive functions such as perception, memory, attention and motor skills, and also looks at how these processes are implemented in the brain. This kind of research can make use of psychophysiological measurements such as EEG, ECG, and GSR. These measurements, if used according to the standard guidelines, involve a negligible risk and therefore fall into category D.
Accidental discoveries: When using EEGs and ECGs, it is possible that accidental discoveries may be made. This should be stated on the various documents (recruitment documents and the information brochure). In addition, a special section for these measurements should be included on the informed consent form.
Deception and debriefing: Some research involves making use of an implicit manipulation, such as when learning motor sequences or when presenting subliminal stimuli. During the debriefing, the subject should be informed about this manipulation.
Recruitment of subjects: Some studies, for instance research into the processing of pain stimuli, or the registration of EEG, involve procedures which are to some extent unpleasant. Subjects should already be informed about this during the recruitment. Furthermore, sometimes stimulus material is used which is insulting, offensive or, for some people, inappropriate (e.g. photographs of victims of a violent crime, explicit sexual photographs, etc.). This should also be reported during the recruitment.

Specific type of standard research: Psychophysics/Behavioural research
The majority of the research conducted by the CPE department falls into this category. This involves experiments in which the subject is confronted with visual, auditory, tactile and pain stimuli which can either be presented separately or simultaneously. The task is usually aimed at processes relevant to perception, attention, memory and motor skills. In most cases, the subject sits in front of a computer monitor and sometimes also a number of loudspeakers, or the subject has a number of tactile stimulation devices attached to one or more fingers. Tactile stimuli are presented via dismantled 8 Ohm loudspeaker cones. These are taped onto the ring and index fingers of both hands, and driven by Presentation software. In addition, the vibrations presented are amplified by two EC-approved mini amplifiers E-SA9. Usually, the subject in these experiments has to press buttons with one or more fingers, depending on which stimulus is presented. The subject does not sit in this set-up for longer than four consecutive hours, nor does (s)he participate in this kind of research more than three times a week. The head is not fixed for this. The subject is observed via a closed-circuit camera and no recordings are made of the subject. The stimulus material used falls roughly into two categories:

a. It is emotionally neutral: visual stimuli consist of abstract forms or simple images; sounds presented are words, tones, or noise for instance; tactile stimuli consist of short vibrations. In all cases, the stimulus intensity used does not exceed any critical limit (e.g. 100 lumen / 100 dB).
b. It is emotionally charged: the stimuli are developed to specifically elicit particular emotions. In this case, only stimuli from standard stimulus-sets (IAPS, IADS) may be used, normal human faces expressing particular emotions, and pain stimuli such as those used in research into nociception. In the case of pain stimuli, use should be made of EC-certified stimulation equipment especially developed for this purpose and the research should be conducted by an experienced researcher in this field. Previous research with similar stimuli has been evaluated positively by the Roessingh METC. The following aspects were specified. The different levels at which the electric stimuli are presented are determined individually in a pre-test. The strength of the electrical current is determined for the level at which a stimulus can first be detected (sensory threshold; VAS-score 1), the level at which the stimulus is experienced as uncomfortable (pain threshold; VAS-score of about 5), and the level at which the stimulus is experienced as extremely painful (pain tolerance level; VAS-score of about 9). The stimuli for the experiment are then set to a level well below the pain tolerance level (VAS-score of about 7). The number of pain stimuli above the pain threshold is kept low (< 200) and there is an interval of at least 3 seconds between these stimuli. Subjects are screened for possible oversensitivity and should not partake of any drugs or alcohol in the 24 hours preceding participation. Furthermore, mood assessment questionnaires are filled in prior to and after completion of the experiment. Participants are informed quite explicitly that they can decide at any time and without giving any reason whatsoever to withdraw from the experiment. There are no adverse consequences linked to this. In the unlikely event that any harmful effects do occur after all, e.g. spontaneously reported by the participant or observed by the researcher, then these will be noted and reported to the CE. The researcher and/or the UT has a third party liability insurance which is in accordance with legal conditions in the Netherlands (Article 7 WMO and the rules for Compulsory Insurance in Medical Research Involving Human Subjects 23 June 2003). This insurance covers possible losses suffered by research participants due to injury or death which may have resulted from the research.

Specific type of standard research: Psychophysiological research (EEG, EOG, ECG, EMG)

In this research, use is usually made of stimuli as described in the type of research detailed above, whereby the head of the subject is fitted with an elastic cap (Easy-Cap; Falk Minow Services, Herrsching, Germany). Up to a maximum number of 64 Ag/AgCL ring electrodes are attached to this cap for recording the electro-encephalogram (EEG). Different referencing methods are used for the signal such as mastoids, earlobes, but usually the online average is taken as a reference. An earth electrode is also used. This allows free movement of the head. In addition, electrodes are usually attached around the eyes in order to register eye movements (the electrooculogram: EOG), and sometimes electrodes are also placed to measure the heart rate (the electrocardiogram: ECG) and muscle activity (the electromyogram: EMG). The electrodes are attached as specified in the Electro-Cap instruction manual. The physiological signals are amplified using a 72-channel amplifier (QuickAmp; BrainProducts GmbH) and Vision Recorder is used for further acquisition of the signals. Work is carried out according to the guidelines set out in the instruction manual of Easy-Cap. All equipment or materials used comply with required EC guidelines. The subject does not participate for longer than four hours at a time, with regular breaks (every 20 minutes or so). Furthermore, the subject may not participate more than twice a week in a similar experiment.

Specific type of standard research: Psychometric research

A few research studies involve questionnaires or interviews which can be regarded as standard research. However, in the case of patient groups who meet the DSM-IV criteria, for example, there may be cause for a strongly emotional state, and the proposed research should be examined more closely. A number of characteristics of the questionnaire research method are the following:

a. Respondents individually fill in answers, in writing or electronically, to questions about themselves, their environment or others in their environment. Completing the questionnaire takes no longer than 1 hour.
b. Questionnaire subjects include cognitive skills (memory, language proficiency, numerical proficiency, IQ), learning styles, autobiographical memories, personality traits, health, use of medicines/drugs or psychoactive substances, mood, attitudes, opinions, emotional experiences, etc.
c. Deception is only allowed here if subjects are informed about it after the research has ended, in such a way as to eliminate possible negative effects resulting from the deception.
d. With questions on emotional or sensitive topics (for instance, traumatic experiences), the researcher is responsible for ensuring that these are phrased in such a way that neither the subject nor others in the subject's environment will experience any adverse effects. The questions in the research should always be of a neutral nature and therefore not judgemental.
e. No physical discomfort or health and safety risks are involved.

5.3.2 Department ELAN

ELAN – Education for Scientific Citizenship

ELAN's research program aims to investigate the role of and ways of understanding and promoting scientific citizenship in education and communication settings, in formal as well as informal contexts. The research is not medical by nature. The research environment is the actual school or professional environment, whereby groups of pupils, teachers or other professionals act as participants. School principals and individual teachers are kept informed of the nature and scope of the studies. In consultation with the responsible principals and teachers, the manner in which parents of pupils will be informed of forthcoming experiments is established. Depending on the nature of the study (didactic intervention or survey study), parents are given an outline of the planned research and are given the opportunity to grant permission for their child to participate or not.

Authorization EC: assessment of ethical permissibility by EC or by MEC: The standard research of ELAN/ poses questions are not of a medical nature. In general, the questions are concerned with the normal functioning of children and adults with regard to learning, attitudes, reasoning and decision-making. The questions for teachers and/or school principals could also concern their relationships, with their colleagues. This could include, but is not limited to, the nature/content and frequency of the relationship.

Selection of subjects and participation: The subjects of studies are adults and students in different educational settings (ranging from primary schools to universities). Adult subjects are recruited via direct contact with schools. They participate voluntarily in the research, and in some cases are remunerated for their participation. This is not necessarily the case for research carried out in schools. With student participants, the school principals and teachers are informed of the nature and scope of the study. The way in which the parents/care takers of the children are informed and their permission requested for the participation of their child in the experiments, is determined in consultation with the responsible school personnel.

Screening of subjects: Specific inclusion or exclusion criteria can be employed for the selection of subjects. These criteria are decided on the basis of the specific need of the study and they are decided on in collaboration with the participating schools or other institutions that contribute to the study.

Accidental discoveries: Information that is accidentally discovered and that is not relevant for the studies undertaken is not disclosed to third parties.

Informed consent and Information brochure: Participants in our studies (or their legal representatives if participants are under 18 years of age) will be informed about the research by an *information brochure or orally by the researcher and have an opportunity to ask questions*. After receiving the information, they are required to sign an *informed consent form*. If the research takes place at a school, this procedure can also be carried out via the teachers or principals, who inform the

parents/care takers. The informed consent procedure may take on the form of passive approval. Based on the information given, parents/care takers have the opportunity to indicate any objections. If they do not do so before a given date, then they have implicitly given their consent. Sufficient time must be given to the parents/care takers to react.

Specific type of standard research: Didactic/intervention research

In this type of research, participants are confronted with various types of teaching and learning methods or learning materials that may include traditional materials or digital learning environments. Tasks may consist of individual learning assignments or group work with one or more other participants. Different teaching or learning conditions may apply, in which the effects of different types of instruction or support methods are investigated and compared to other conditions or a control condition. If the research is conducted in schools, care is taken that the various instructions do not put participants in one condition at an advantage or disadvantage in their general functioning at school compared to subjects in other conditions. Because the duration of the interventions is generally short, this will usually not be any reason for concern. Pre-tests and post-tests may take the form of knowledge or competency test, questionnaires (e.g., motivation, attitudes, personality) or other specific tests (e.g., intelligence tests, aptitude tests, neuro-psychological tests). In the (collaborative) digital learning environments, a chat system is sometimes used. In some cases audio or video recording are made. The contents of the chats, as well as the thinking out loud protocols and computer log files, audio and video recordings can serve as objects of analysis but will be treated anonymously.

Specific type of standard research: Organizational and professional development in schools.

In this type of research, teacher professional development is studied in the context of teachers' work environment. This might concern teachers' daily and natural work context or a longitudinal and collaborative group setting in which interventions are instigated by the researchers in order to bring about certain (learning or teaching) results in the school practice. The work of the teaching professionals is documented. This can be done by direct observations, video and audiotapes or by studying process documentation. Additionally, questionnaires, sociometric questionnaires, and interviews may be used to collect data on participants' perceptions of the work, their relationships with their colleagues, and/or results of the interventions.

Participants are informed ahead of time, either at the beginning of the intervention or at the time of the data collection activities, about the research purpose and the consequences of the study. They have the option to stop their participation at any point in time.
The data collected are made anonymous. Data obtained from individuals are not communicated to third parties in their original form. Results are only communicated on a group level and with utmost care to ensure that findings will not be able to point to specific participants. Only the researcher involved in the data collection has access to information linking data to specific subjects. Any personal details are destroyed as soon as this is possible.

5.3.3 Department of Instructional Technology (IST)

Explanatory notes about fulfilled general requirements and conditions
The department carries out research among other things on the effectiveness of modern didactic methods in which ICT tools often play a role. The research is not medical by nature. The experimental environment is a school classroom in vivo whereby groups of pupils act as subjects. The school heads are kept informed of the nature and scope of the didactic experiments. In consultation with the school heads, the extent to which it is sufficient to inform parents of forthcoming experiments in which the drastic nature of the experimental didactic method with regard to the method in force is the criterion, is constantly assessed.

Authorization CE: assessment of ethical permissibility by EC or by MEC

The standard research of IST poses questions which are not of a medical nature. In general, the questions are concerned with the normal functioning of the human being in relationship to learning, reasoning and decision-making. The department carries out research on the effectiveness of modern didactic methods in which information technology often plays an important role. The subjects are pupils in primary and secondary education, and pupils/students in senior secondary vocational education, higher professional education and at university. School classes are regularly used as groups in research. The school heads are kept informed of the nature and scope of the didactic experiments. The way in which the parents/carers of the children are informed and their permission requested for the participation of their child in the experiments is determined in consultation.

Selection of adult, competent persons: Subjects participate voluntarily in the research and are remunerated for their participation. This is not necessarily the case for research carried out in schools. Remuneration can be in the form of a small gift, an amount of money or so-called human subject points. Remuneration can also be in the form of a reciprocal service to a school (e.g. a presentation or providing information). Subjects are recruited via direct contact with schools, advertisements, posters or via the SONA system [web-based human subject pool management software for universities].

Screening of subjects: If the research so requires, some subjects are excluded from participation in the research. This could be on the basis of the presence of dyslexia, dyscalculia, attention deficit or other problems which make learning difficult. Further screening can be on the basis of vision problems, for instance in experiments where eye movements are registered or experiments where colour perception is important. Furthermore, specific inclusion or exclusion criteria can be employed for the sake of matching with other subjects on the basis of gender, foreknowledge or intellectual capacities for example.

Accidental discoveries: In the case of EEG measurements, a provision is included in the informed consent for a procedure to be followed should any abnormalities be found in the EEG which could possibly indicate a disorder (e.g. epilepsy). The subject should provide the name and location of his/her general practitioner, or the full address of the GP's surgery or group practice to be notified in the event of a discovery that may be of vital importance to the subject. Should the subject not have a general practitioner, then (s)he should agree to a student medical service doctor or, more commonly, a company doctor being notified. The subject must agree to this procedure and acknowledge this by signing a separate clause on the informed consent form.

Informed consent and Information brochure: The subject (or his/her legal representative if the subject is under 18 years of age), after taking cognizance of the *information brochure* accompanying the research and prior to participation in the research, signs an *informed consent form*. If the research takes place in a school, this procedure can also be carried out via the school heads who inform the parents/carers thus providing, together with the researchers, a kind of passive approval. Parents/carers are obliged to indicate any objections. If they do not do so before a given date, then they have implicitly given their consent. Sufficient time must be given to the parents/carers in which to react.

Specific type of standard research: Didactic research

In this kind of research, subjects perform learning tasks which usually make use of digital learning environments. These can be an individual learning task or a task which should be performed together with one or more other subjects. Different conditions may apply in which the effect of a certain type of instruction or support is investigated. If the research is conducted in schools, care is taken to ensure that these instructions do not put subjects belonging to a certain condition either at an advantage or disadvantage in their functioning at school in relation to subjects belonging to other conditions. Taking the duration of the experiments into account, this is seldom likely to be the case. Pre-tests and post-tests, questionnaires (motivation, personality) or other specific tests (for instance intelligence tests, aptitude tests, neuro-psychological tests) may form part of the didactic research. In the (collaborative) learning environments, use is sometimes made of a chat system. The content of the chats, as well as the thinking out loud protocols and computer log files can serve as objects of analysis.

Specific type of standard research: Psychophysiological research
This kind of research is carried out with the help of EEG and eye movement registration. Use is primarily made of visual stimuli which are related to aspects of digital learning environments (e.g. representations).

Specific type of standard research: Usability studies
Usability studies are studies in which learning environments are examined for their user friendliness. Subjects pass through a learning environment according to a set protocol and thereafter answer questions via questionnaires or semi-structured interviews on their experiences with the learning environment. This type of research is intended to optimize the design of learning environments.

5.3.4 Department of Media, Communication and Organization (MCO)

Explanatory notes about fulfilled general requirements and conditions

Authorization EC: assessment of ethical permissibility by EC or by MEC: The standard research of MCO poses questions which are not of a medical nature. In general, the questions are concerned with the normal functioning of the human being in relationship to media, communication and organizations. Two research areas can be distinguished within the Department of Media, Communication & Organization: e-Government and media psychology.

Specific type of standard research: Questionnaire-based research and qualitative research (field research)
a. Respondents individually fill in answers, in writing or electronically, to questions about themselves, their environment or others in their environment (friends, partner, fellow students, etc.) or are questioned orally either individually or as part of a group (focus group).
b. No observation of behaviour takes place and no physiological measurements are taken.
c. The real purpose of the research is not always disclosed to the participant prior to the research in order to prevent, among other things, socially desirable responses. The real purpose of the research is however always explained to the participant during the debriefing.
d. Deception is allowed only if participants are fully informed at the end of the research about the manner in which they have been misled during the research. The following form of deception is often used: giving false feedback on personality/abilities provided that no lasting harmful effects are anticipated.
e. Completing the questionnaire should not take longer than 1 hour; interviews and focus groups should not take longer than 2 hours.
f. No physical discomfort or health and safety risks are involved.
g. Content of frequently asked questions in MCO questionnaires and interviews includes: attitudes, opinions and preferences with regard to the use of media; emotional experiences/expressions with regard to particular media utterances; behaviour or behavioural intentions with regard to use of media; self-efficacy with regard to the use of media technology; motives for media use; personality factors.
h. If questions are asked about emotional or sensitive topics (such as aggression, addiction, etcetera), the researcher is responsible for ensuring that the questions are formulated in such a way that neither the participant nor others in the participant's environment will experience any adverse effects. The questions posed in the research should always be of a neutral nature and therefore not judgemental.

Specific type of standard research: Laboratory research
a. Procedure: Participants are exposed to stimuli (usually video fragments or other visual material) or they play a game. Their behaviour in reaction to the stimuli is measured by recording the behaviour and/or by letting participants fill in questionnaires.
b. No physiological measurements have been taken to date, but this will take place in the near future.

c. The real purpose of the research is not always disclosed to the participant prior to the research in order to prevent, among other things, socially desirable responses. The real purpose of the research is however always explained to the participant during the debriefing.
d. The following form of deception is often used: suggesting a particular task (for instance evaluating stimuli) whilst the actual measurement involves behaviour(al intentions), aroused emotions or memory abilities.
e. Laboratory research should not take longer than 1 hour.
f. No physical discomfort or health and safety risks are involved.
g. Stimuli which are presented are often (1) video fragments to induce emotions/moods (mood/emotion manipulation), (2) games (including first-person shooters).

5.3.5 Department of Marketing Communication & Consumer Psychology (MCP)

Explanatory notes about fulfilled general requirements and conditions

Authorization EC: assessment of ethical permissibility by EC or by MEC: The standard research of MCP poses questions which are not of a medical nature. In general, the questions are concerned with the normal functioning of the human being in different situations such as (online or offline) sales situations, waiting rooms, public spaces, and interpersonal relations and groups.
Anonymity of respondents is guaranteed, and the respondent does not fill in any information which reveals or could reveal his or her identity. Results are always made anonymous for reports or feedback. For research carried out on assignment, results are always reported to the client in such a way that (s)he cannot identify individuals.

Specific type of standard research: Questionnaire-based research (field research)
Respondents individually fill in answers, in writing or electronically, to questions about themselves, their environment or others in their environment (friends, partner, fellow students, etc.), whether individually, as a group or in a class. Usually no observation of behaviour takes place and no physiological measurements are taken.
The real purpose of the research is not always disclosed to the participant prior to the research in order to prevent, among other things, socially desirable responses. The real purpose of the research is however always explained to the participant during the debriefing. Completing the questionnaire should not take longer than 1 hour. No physical discomfort or health and safety risks are involved.
Frequently asked questions in questionnaires relate to: personality traits (e.g. Need for Cognition, Need for Structure, aggression, dominance), attitudes, stereotypes, opinions and preferences; experiences (e.g. as a result of physical disabilities or ailments); emotions, cognitions, and behaviour in social interactions (e.g. sales situations); autobiographical memories (e.g. the last time that the subject was insulted in public); etc. If questions are asked about emotional or sensitive topics (such as conflicts, sexual behaviour, etcetera), the researcher is responsible for ensuring that the questions are formulated in such a way that neither the participant nor others in the participant's environment will experience any adverse effects. The questions posed in the research should always be of a neutral nature and therefore not judgemental.

Specific type of standard research: Laboratory research
Procedure: Participants are exposed to stimuli, either alone or together with a number of other people at the same time. Their behaviour in reaction to the stimuli is measured by reaction time paradigms, and/or the recording of behaviour (e.g. facial expressions of emotions) via a video camera, and/or via eye tracking. Subjects also sometimes have to make choices, pass judgement or perform short tasks (for instance in order to conceal connections between test sections or to lower the chance of answer consistency). In addition, participants often have to fill in questionnaires in which, in principle, the same questions can be asked as those named under standard research “Questionnaire-based research”.

Only the researcher and his/her staff have access to the identifiable data, and audio and video recordings are not made available to third parties; recordings in which subjects are identifiable are carefully stored and are destroyed when no longer needed for the purposes of the research.

The following forms of deception are often used:
- Participants are not always informed prior to the research of the actual or entire purpose of the research in order to avoid, among other things, the influence of social desirability. The real purpose of the research is however always explained to the participant during the debriefing.
- Participants are sometimes given manipulated feedback (false feedback) on personality/abilities or achievements when performing a task, provided that no lasting harmful effects are anticipated. In all cases, subjects are informed about this later on.
- The participants are sometimes told that they are interacting with other subjects whilst this is not actually the case.
- The participants are sometimes told that certain tasks need to be performed whilst this is not so (no extremely unpleasant or burdensome tasks).
- Use is often made of one or more confederates who play a particular role in the interaction with participants who are unaware of this.

Laboratory research generally does not last longer than 1 hour. No physical discomfort or health and safety risks are involved. Stimuli which are not subliminally presented are often (1) environments, texts, images, film fragments which induce emotions/moods (mood/ emotion manipulation), and/or (2) behaviour of a confederate.
Stimuli which are subliminally presented are often pictures and/or words with either emotional or neutral connotations/meaning (such as 'violence', 'flower').
Stimulus material is not, by reasonable standards, to be regarded as shocking, frightening, or insulting. It is possible that the stimulus material is emotionally charged; in other words it is specifically developed to arouse particular positive or negative emotions. Then it is reasonable to expect that it will arouse particular emotions.
In experiments where subjects participate in groups (or dyads), there shall be no physical contact between the subjects. In experiments where conflicts are simulated (such as research on negotiation or conflict management), the experiment will always be terminated if there is any threat of physical or verbal abuse (swearing, shouting).

5.3.6 Department of Educational Organization & Management (O&M)

Explanatory notes about fulfilled general requirements and conditions
The department carries out research into the effectiveness of schools whereby learning achievements are measured, either separately or in combination with school characteristics (at classroom level and school level) and/or characteristics of educational systems. Generally this is done by means of pen and paper questionnaires and with the help of interviews. Respondents participate on a voluntary basis. Schools are always informed about the nature and objective of the research in question when asked to participate in the research. Moreover, anonymous data processing and research results reports are guaranteed.
At the present time, medical and physiological subjects are not applicable. What does apply to all research is that participation is on a voluntary basis and participants receive information about the setup and purpose of the experiment.

5.3.7 Department of Research Methodology, Measurement and Data Analysis (OMD)

Explanatory notes about fulfilled general requirements and conditions
The department carries out research of a diverse nature and setup, both with and without subjects, which cannot be described as standard research. Proposed research can correspond to standard research such as is described in other departments.

5.3.8 Department of Organizational Psychology and Human Resource Development (OP&HRD)

Explanatory notes about fulfilled general requirements and conditions

Authorization EC: assessment of ethical permissibility by EC or by MEC: The questions posed by the standard research of A&O and HRD are never of a medical nature. In general, research is carried out on the behaviour of staff within organizations, including schools. This also does not involve any medical procedures. Research is in the form of questionnaires or otherwise involves experimental research.

Specific type of standard research: Laboratory research: Questionnaire-based research: Cross-sectional individual survey without linked data (field research)
Respondents individually fill in answers, in writing or electronically, to questions about themselves, their environment or others in their environment (staff, boss, colleagues, friends, etc.). No physiological measures are made. Participation is on a voluntary basis and is usually not remunerated, or the remuneration is not disproportional (maximum €10 per hour). Filling in generally does not take more than 1 hour.
There is always an accompanying letter or email with an explanation about the research. This should certainly indicate who is carrying out the research, or in the case of research on assignment, who the client is, the purpose of the research insofar as this is possible, and what will happen to the data collected. If questions are posed about emotional or otherwise sensitive topics (such as psychological problems, illness, informal relationships, conflicts, what has been learnt from following a training course etc.), then this is stated in the accompanying written material in such a way that the respondent can assess beforehand whether or not he or she wants to participate in this research. The questions posed are in all cases neutral and therefore not judgemental. The respondent may at all times refuse to fill in the questionnaire or parts of the questionnaire.
Confidentiality of the data collected from respondents is guaranteed. Results are always made anonymous for reports or feedback. For research carried out on assignment, results are always presented to the client in such a way that (s)he cannot identify individuals.

Specific type of standard research: Questionnaire-based research: Cross-sectional surveys with linked data and longitudinal surveys (field research)
The general provisions are fulfilled except the provision that the respondent does not fill in any information which could reveal his or her identity. After all, this information is necessary in order to link the data from the questionnaire to other data. The following links are standard:
a. Links to administrative data (e.g. with regard to unexplained absence or productivity).
b. Links to data obtained from other respondents (e.g. fellow team members, subordinates, supervisors).
c. Links to data obtained previously from the same respondent (in longitudinal research).
d. A combination of what is stated under a, b and c.

If respondents are identifiable then the following applies:
a. Only the researcher has access to the identifiable data.
b. The personal details are destroyed as soon as this is possible (that is to say, as soon as linking the data is completed).
c. In general, the researcher must operate in accordance with privacy legislation.

If data are linked to other sources (e.g. data from other respondents, administrative data), then the respondent is informed of this prior to linking the data. On the basis of this information, the respondent may refuse to fill in the questionnaire or allow the linking to actually take place. In longitudinal surveys, no more than 5 measurements take place, and not more than 1 measurement per month.

Specific type of standard research: Experimental research, individual

Subjects in the laboratory of the Faculty of Behavioural Sciences perform simple tasks individually whereby the performance thereof is observed and/or the results are recorded. Such tasks include: generating ideas, making choices, passing judgements, and other tasks which are emotionally neutral. The stimulus material used for this is likewise emotionally neutral. The purpose of the research is not to place subjects under a lot of pressure to achieve or to put them under high levels of stress. No physiological measures are made.
No physical discomfort or health and safety risks are involved. The research does not last longer than 1 hour at a time and subjects are not tested more often than once a month. Data collected from subjects is treated confidentially. If this is not possible (e.g. with audio and video recordings), then the following applies:

a. Only the researcher and his/her staff have access to the identifiable data, and audio and video recordings are not made available to third parties.
b. The personal details are destroyed as soon as possible.
c. The respondent gives permission for these recordings on the informed consent form.
d. In general, the researcher acts in accordance with the privacy legislation.

Deception is allowed only if participants are fully informed at the end of the research about the manner in which they have been misled during the research. This debriefing must at any rate be such that it can be reasonably assumed that any possible negative effects as a result of the deception are eliminated. For instance, it must be clear that any false feedback on intelligence was in fact untrue and that the researcher does not possess an actual intelligence score for the subject. The following forms of deception are allowed:

1. Giving false feedback provided that no lasting harmful effects may be anticipated.
2. The suggestion of interaction or future interaction with others whilst this does not take place.
3. The suggestion that certain tasks need to be performed whilst this is not so, provided no extremely unpleasant or burdensome tasks are suggested.

Specific type of standard research: Experimental research involving groups and dyads
This concerns experiments such as those mentioned in experimental research, individual. There is no physical contact between subjects. In experiments where conflicts are simulated (such as research on negotiation or conflict management), the experiment will always be terminated if there is any threat of physical or verbal abuse (swearing, shouting).

5.3.9 Department of Psychology & Communication of Health & Risk (PCGR): sub-department of Conflict, Risk & Safety

Explanatory notes about fulfilled general requirements and conditions
Information about general requirements, conditions and types of research is available.

Department of Conflict, Risk & Safety (PCRS)

Authorization EC: assessment of ethical permissibility by EC or by MEC: The standard research of PCRS poses questions which are not of a medical nature. In general, these questions are concerned with the normal functioning of a human being in different interpersonal and group situations, such as in negotiations and conflicts or when working together under time pressure, and we examine attitudes in relation to social risks. The anonymity of respondents is guaranteed, and the respondent does not fill in any information which reveals or could reveal his or her identity. Results are always made anonymous for reports or feedback.

Specific type of standard research: Questionnaire-based research and qualitative research (field research)

a. Respondents individually fill in answers, in writing or electronically, to questions about themselves, their environment or others in their environment (friends, partner, fellow students, etc.) and are questioned orally or observed individually or as part of a group.
b. In some cases, audio or video recordings are made of the interview or the behaviour of respondents to be observed. Only the researcher and his/her staff have access to the identifiable data, and audio and video recordings are not made available to third parties without the express written permission of the respondents concerned; recordings in which subjects are identifiable are carefully stored and are destroyed when no longer needed for the purposes of the research.
c. Completing the questionnaire should not take longer than 1 hour; extended interviews (for example with police negotiators) may not last longer than one session (morning, afternoon).
d. No physical discomfort or health and safety risks are involved.
e. Content of frequently asked questions in questionnaires and interviews: attitudes, opinions and preferences with regard to risks such as floods or terrorism, behaviour during conflicts or negotiations, opinions on security issues (e.g. surveillance cameras or metal detector gates) and personality factors. Important with group observations is the team cohesion and the attitude toward the leader.
f. If questions are asked about emotional or sensitive subjects (such as conflicts, bullying, aggression), the researcher is responsible for ensuring that the questions are formulated in such a way that neither the participant nor others in the participant's environment will experience any adverse effects. The questions posed in the research should always be of a neutral nature and therefore not judgemental.

Specific type of standard research: Laboratory research

a. Procedure: Participants are exposed to stimuli (usually video fragments or other visual material) or play a game (for example a negotiation game). Their behaviour in reaction to the stimuli is measured by recording the behaviour and/or by asking participants to fill in questionnaires. The behaviour can be recorded on audio or video. Only the researcher and his/her staff have access to the identifiable data, and audio and video recordings are not made available to third parties; recordings in which subjects are identifiable are carefully stored and are destroyed when no longer needed for the purposes of the research.
b. The real purpose of the research is not always disclosed to the participant prior to the research in order to prevent, among other things, socially desirable responses. The real purpose of the research is however always explained to the participant during the debriefing.
c. Deception is allowed only if participants are fully informed at the end of the research about the manner in which they have been misled during the research. The following forms of deception are often used:

- Suggesting a particular task (for instance solving a puzzle), whilst the actual measurement is really about induced emotions or behaviour and behaviour(al intentions) such as information seeking behaviour or deviant behaviour (e.g. leaving rubbish behind).
- Participants are sometimes given manipulated feedback (false feedback) on personality, abilities or achievements when performing a task, provided that no lasting harmful effects are anticipated; in all cases, subjects are informed about this later on.
- The participants are sometimes told that they are interacting with other subjects or will be interacting with other subjects, whilst this is not actually the case.
- Use is sometimes made of one or more confederates who play a particular role in the interaction with participants who are unaware of this.

d. No physiological measurements are being made as yet but this will take place in the near future.
e. Laboratory research should not take longer than 1 hour.
f. No physical discomfort or health and safety risks are involved.
g. In experiments where conflicts are simulated (such as research on negotiation or conflict management), the experiment will always be terminated if there is any threat of physical or verbal (swearing, shouting) abuse.

Specific type of standard research: Questionnaire-based research: Cross-sectional surveys with linked data and longitudinal surveys (field research)

The general provisions are fulfilled, except the provision that the respondent does not fill in any information which could reveal his or her identity. After all: this information is necessary in order to link the data from the questionnaire to other data. The following links are standard:

a. Links with administrative data (e.g. with regard to unexplained absence or productivity).
b. Links to data obtained from other respondents (e.g. fellow team members, subordinates, supervisors).
c. Links to data obtained previously from the same respondent (in longitudinal research).
d. A combination of what is stated under a, b and c.

If respondents are identifiable then the following applies:

a. Only the researcher has access to the identifiable data.
b. The personal details are destroyed as soon as this is possible (that is to say, as soon as linking the data is completed).
c. In general, the researcher must operate in accordance with privacy legislation.

If data are linked to other sources (e.g. data from other respondents, administrative data), then the respondent is informed of this prior to linking the data. On the basis of this information, the respondent may refuse to fill in the questionnaire or allow the linking to actually take place. In longitudinal surveys, no more than 5 measurements may take place, and not more than 1 measurement per month.

5.3.10 Department of Technical and Professional Communication (TPC)

Explanatory notes about fulfilled general requirements and conditions

The department carries out research on communication processes and messages with the emphasis on the effectiveness thereof. The aim is to describe the characteristics which exert an influence on this effectiveness.

Authorization EC: assessment of ethical permissibility by EC or by MEC: Medical research is not applicable.

Selection of adult, competent persons. This is usually the case with the possible exception of any first-year Bachelor's student who might still be a minor (i.e. under 18). In a few cases, the research may involve minors as subjects, namely:

1. When minors form a specific target group for the documents to be investigated, or
2. When organizations are involved in which minors are specific stakeholders (an example of this is the research on maintaining age limits for the sale of alcohol and tobacco). In the aforementioned, minors are in fact not only the object of the research but are also the subject. Minors are only involved in research after obtaining informed consent from them and their parents.
3. When minors respond to a general request to participate in research (survey or log registration).

Voluntariness of participation: Subjects are not put under any pressure to participate. The remuneration is not higher than the standard remuneration.

Screening of subjects: Subjects are screened insofar as that is necessary in order to guarantee that the random sample is representative of the research population.

Accidental discoveries: These are not applicable in a medical sense.

Informed consent: This is usually applicable. Where observation is involved (whether electronically or not) and where the data can be linked to individual persons, permission to use the data is requested afterwards. For the use of publically accessible texts (such as weblogs, contributions to discussion forums), no informed consent is requested, although the texts are anonymized in the research report.

Anonymity: Research data of persons is made anonymous at the earliest possible stage, and certainly in the research report, unless the person concerned has given express permission not to do so. The use of video recordings for purposes other than obtaining and analysing results is only possible with the written permission of the persons concerned.

Deception and debriefing: Deception occurs in a number of studies in the sense that the purpose of the research is concealed in order to prevent it influencing the behaviour of the subjects. This is the

case, for instance, when observing document processing behaviour or in 'mystery shopping' research. Usually, debriefing takes place afterwards.
Recruitment of subjects: Risks such as those listed under a and b are not applicable. Risks such as those listed under c may be applicable for tasks where subjects must search for information in open sources such as the Internet for instance. Subjects will be informed if these risks are greater than those found in the normal work, learning or home situation.

Specific type of standard research: Observation of document processing/thinking out loud
Subjects are asked to perform a particular task and/or to answer questions based on one or more documents. Where personal information (for instance income details for filling in a form) is required, use is normally made of a fictitious situation.
When performing the task, the subject can be asked to 'think out loud' in order to get a better idea of the way in which the task is performed, the deliberations of the subject when making decisions, the misunderstandings or problems which arise when implementing the task and possible irritations connected with performing the task.
During the task, subjects can be asked questions at different moments about the cognitive effort, the motivation or the appreciation of the task.
The behaviour of the subjects is recorded by means of audio or video recordings, registration of keystrokes and mouse movements, and notes made by the research leader.
At the end of the task, subjects can be asked about their experiences while performing the tasks, their opinion about the materials used and other task-related aspects.
Either before or after performing the task, questions can be asked about personal characteristics relevant to the research.
The registrations are stored and processed in such a way that the individual subjects are not identifiable except by the researcher, and then only insofar as this is necessary in order to be able to verify information or obtain additional information at a later date. This means that protocols and recordings (video or sound) are kept confidential and that only the research leader knows which recording belongs to which subject. In the written protocols, names and other elements which could lead to recognition are replaced by terms such as [name], [name company], [social security number].

Specific type of standard research: Questionnaire-based research
Respondents individually fill in answers, in writing or electronically, to questions about communication tools or processes, and in relation to these, about themselves, their environment or others in their environment.
Usually no observation of behaviour takes place and no physiological measurements are made. The real purpose of the research is not always disclosed to the participant prior to the research in order to prevent, among other things, socially desirable responses. The real purpose of the research is however always explained to the participant during the debriefing. Completing the questionnaire should not take longer than 1 hour. No physical discomfort or health and safety risks are involved. Frequently asked questions in questionnaires of the Communication Programme group are: personality traits (e.g. Need for Cognition, Need for Structure, aggression, dominance), attitudes, stereotypes, opinions and preferences; experiences (e.g. as a result of physical disabilities or ailments); emotions, cognitions, and behaviour in social interactions (e.g. sales situations); autobiographical memories (e.g. the last time that the subject was insulted in public); etc. If questions are asked about emotional or sensitive topics (such as conflicts, sexual behaviour, etcetera), the researcher is responsible for ensuring that the questions are formulated in such a way that neither the participant nor others in the participant's environment will experience any adverse effects. The questions posed in the research should always be of a neutral nature and therefore not judgemental.

Specific type of standard research: Oral interviews (face-to-face)
Respondents individually answer questions on communication processes or communication tools. Usually no observation of behaviour takes place and no physiological measurements are made. The real purpose of the research is not always disclosed to the participant prior to the research in order to

prevent, among other things, socially desirable responses. The real purpose of the research is however always explained to the participant during the debriefing. An interview usually takes no longer than 1 hour.
No physical discomfort or health and safety risks are involved. An interview may be recorded on audio or video, but only if the interviewee has given permission beforehand. The registration is kept and processed in such a way that the individual subjects are only identifiable by the researcher, and then only insofar as this is necessary in order to be able to verify information or obtain additional information at a later date. This means that protocols and recordings are stored anonymously and that personal details are rendered unrecognizable.

Specific type of standard research: Oral interviews (telephonic)
Respondents individually answer questions on communication processes or communication tools. At the start of the interview, the interviewer introduces himself with his name and organization name (University of Twente) and verifies whether it is convenient to hold the interview at this particular moment. If necessary, an appointment is made for another time. For the rest, the rules for the face-to-face interview apply.

Specific type of standard research: Group interviews
Respondents answer questions in a group setting on communication processes and communication tools. The research leader is responsible for creating a safe atmosphere in the group and for an open discussion; (s)he tries to prevent participants being embarrassed or otherwise experiencing emotional damage as a result of the behaviour of other participants. The interaction within the group is not itself a subject of the research. The points listed in b through to g under Oral Interviews are also applicable to group interviews.

Specific type of standard research: Text analytics research and conversation analysis
Documents are analysed with the purpose of identifying, defining and classifying linguistic and textual features, and/or to make statements about their quality based on this analysis.
Public documents may be analysed without obtaining prior permission from their authors. This applies to products of mass media and to documents which are accessible via the Internet without a password or other form of protection. Also non-public documents may be used in text analytics research but only insofar as they have become available to the researcher in a proper manner. The researcher is responsible for ensuring that these documents are not disseminated further and that their content, insofar as this is of a confidential nature, is not made public. When citing researched documents in publications, the usual rules for copyright (source acknowledgement, permission from the party involved to cite texts longer than 250 words) apply.

Specific type of standard research: Participatory observation mystery research
With this method, a company or institute is visited by a person masquerading as a customer without the personnel of the company or institute being aware of this. Institutions and/or personnel serve as research subjects without having giving explicit permission. Standard mystery research should at least meet the following requirements:
with regard to the research units:
- The research units find themselves in a situation in which they can reasonably expect to be seen or heard by others (for instance in a shop).
- The information which is sought is of major public importance.
- Conventional methods would most probably not deliver reliable results.
- Innocent people may not be exposed to any risks. Consequently, care must be taken to ensure the anonymity of the research units/participants.

5.3.11 Department of Curriculum Design & Educational Innovation (C&O)

Information about general requirements, conditions and types of research is not available.

5.3.12 Department of Philosophy (Philosophy)

General research of the department of Philosophy

Explanatory notes about the nature of the research
The standard research of the department concerns the functioning of science and technology, the development of new scientific knowledge and new technologies and the impact that science and technology have (or may have) on (parts of) society. Usually the research is performed by way of literature study or conceptual analysis. Research with human subjects is taking place when it is investigated empirically how technologies are developed, how existing practices of using a technology are functioning and what technology developers, (potential) users and stakeholders think of these practices and new developments. In these cases, the research is mainly qualitative and explorative. Standard methods used are interviews (oral and by telephone), group interviews, observations, focus groups, stakeholder workshops and text analysis of documents.

Authorization CE: assessment of ethical permissibility by EC or by MEC
The technologies and practices under investigation are sometimes of a medical nature. However, the aim of the research is usually not medical. If the aim of the research might be medical after all, the METC will asked to assess whether the research falls under the scope of the WMO.

Specific type of standard research: qualitative research and questionnaire-based research

Often used types of qualitative research at the department of Philosophy are interviews (face-to-face or by phone), group interviews, observations, focus groups and stakeholder workshops. In addition, sometimes questionnaires are used-. Standard research meets the following qualifications:

a. Respondents individually fill in a questionnaire (on paper or electronically), or will be interviewed or observed, individually or in groups. The purpose of the research will always be announced before the start of the research.
b. In some cases the interview, discussion or the behaviour to be observed of respondents are recorded on audio or video. Respondents will always be asked permission for such recording before the recording starts.. Only the researcher and co-researchers have access to identifiable information, and audio- and video recordings will not be shown to others without explicit permission of the respondent. Recordings which can be linked to the person of participants will be kept secure and safe and will be destroyed as soon as the research project allows. In transcriptions of interviews, observations, focus groups and workshops, participants will not be mentioned by name but with a code.
c. Filling in a questionnaire will last a maximum of one hour. Interviews in general will take no more than two hours.
d. Focus groups and workshops last no more than one day (teach morning/afternoon/evening will have at least one break, and in between there will also be a break). The interaction between the participants can also be subject of investigation.
e. Observations always concern existing practices (situations and practices will not be constructed especially for research purposes). The researcher must identify him-herself as such before the start of the observation. Permission of the participants always must be gained beforehand, if necessary also from the organisation the participants are part of (head of department or board).
f. The research activities will not cause any physical harm to, nor pose any safety- or health risk for the participants.
g. Common topics in questionnaires and oral interviews are: Knowledge of and beliefs about new technologies; ways a technology is used; history of practices; underlying motives and reasons for present ways of doing; views about desirability of innovation of existing practices, norms and values underlying these views.
h. If questions are asked about emotional or sensitive subjects (like psychiatric problems or socially controversial subjects) the researcher will take care to phrase questions in such a way that they are the least confronting as possible.

Specific type of standard research: text-analytic research and conversation analysis

Documents are analysed with the aim to reconstruct and differentiate several ways of thinking and speaking, and/or to determine their quality on the basis of this analysis. Sometimes the interaction between several perspectives can also be the subject of analysis.
Public documents can be analysed without prior permission of their authors. This also applies to products of mass media or documents that are published and accessible on the internet without password or other form of protection. Non-public documents also can be included in text-analytic research, but only if the researcher got access to these documents by asking the author and/or organization for permission. The researcher will take care not to circulate these documents any further and to keep their content, in so far as it is confidential, private–-. The standard rules of copyright apply in case of quoting the investigated documents in a research publication (acknowledging its source, permission of the persons involved for including f texts parts over 250 words).

6. Lists of names and information samples for the EC and (human) subjects

6.1 Names and addresses of the EC members

Ethics Committee, Faculty of Behavioural Sciences, University of Twente
PO Box 217
7500 AE Enschede (NL)
Tel: +31 (0)53 489 4591 email: p.m.groot@utwente.nl
Fax: +31 (0)53 489 2895 website:

List of members of the EC can be found on the webpage:
http://www.utwente.nl/gw/onderzoek/regeling_ethiek/ledenlijst.doc/

6.2 Standard examples of the Information Brochure and Informed Consent Form

Introduction
Every participant in a research trial receives an information brochure and an informed consent form to be signed. The purpose is that:

1. Participants will be informed about the purpose, discomfort, risks, etcetera, of the research in which they will be participating. Participants must be sufficiently informed so that they are able to make a conscious choice as to whether or not to participate in the research.
2. Participants will know that they may withdraw from the research at any time and what will happen to their data, etc.
   The information provided should be correct and tailored to the relevant research. The examples given below are merely meant to serve as illustrations. They should be modified as required to suit the relevant research, particularly with regard to the layout.

Included below are a few examples of information brochures where accidental discoveries are possible (cognitive ergonomics), where parent permission is required in the case of research involving children (developmental psychology) and where passive informed consent applies (developmental psychology). The content and the layout can be modified to suit the relevant research.

6.3 Sample Information Brochure from the CPE department

Enschede, date…..

Information brochure Department CPE

Dear reader,

In this letter, we would like to inform you about the research you have applied to participate in. The experiment will take place on dd-mm-yy, in room xxx of the Cubicus. In the proposed research, entitled "The influence of emotion on processing pain stimuli", brain activity and heart rate are measured, pictures are presented on a screen and pain stimuli are administered at certain moments. The aim of the research is to establish whether the processing of pain stimuli is influenced by an individual's particular emotional state at the time. Is the pain stimulus for instance more painful if you have a simultaneous association with pain, and is the opposite true in the case of a positive emotional state, and can we also localize these effects in the brain? The research could provide important clues to the way in which pain is processed in the brain and indicate possible alternatives to heavy painkillers in combatting pain. In the research, there are a number of important aspects which you should be aware of.
Since physiological measurements are made which can provide information about the functioning of your brain and heart, it is in principle possible to discover specific abnormalities in the EEG or ECG (this occurs very seldom in fact). In such cases, you will be informed about this by the researcher and your general practitioner will be notified. The address details of your general practitioner should thus be made available at the start of the research. If you object to this, you may not participate in the research. You should realize that the research data

obtained will not be scrutinized from a medical perspective. Therefore participation in the research cannot be regarded as a medical test.
In order to register the EEG, use is made of electrodes fitted into a kind of bathing cap placed on the head which record the electrical activity of the brain. In addition, a number of loose electrodes are placed around the eyes and on the collar bone to record eye movements and register the heart rate. Attaching the electrodes to the head will make your hair sticky but after the experiment you can simply wash it out. It is therefore a good idea to bring a towel and also some shampoo.
As a subject in the research, you will be confronted with a number of pictures to induce a particular emotional state. One category of pictures is emotionally neutral, another is positive, and a third is negative. In the second category, the pictures used include sexually tinted images whilst in the third category, pictures include images of a needle being inserted into an arm or a leg.
In addition to the pictures, electric stimuli are regularly administered which in some cases can be experienced as relatively painful. The stimuli are administered via electrodes placed on the left forearm. You determine the strength of these stimuli yourself before the start of the research. These stimulus electrodes can be removed quite simply (even by yourself) with one single movement. It is also relevant for you to know that the setup of all the equipment is completely safe, and that the researcher has plenty of experience with this setup and these kinds of stimuli.
For participation in the experiment it is important that you should not have any history of psychiatric or medical problems, that you are not taking any medication, drugs or excessive amounts of alcohol, and that you have good hearing and sight. Furthermore, you can decide to stop at any point in the course of the experiment without this having any consequences for yourself and without giving any reasons. Any payments 'earned' up until this point will be paid out (in proportion to the duration of participation. In addition, you can still decide at the end of the research and up to 24 hours thereafter, that your data may not be included in the research after all. Other relevant aspects are that your data will be handled in a confidential manner, the anonymity of your data is guaranteed and will never be disclosed to third parties without your permission.
It is important not to smoke or drink coffee for 1 hour before the experiment and not to have alcohol or drugs for 24 hours prior to the experiment. The use of hairspray, wax or make-up is not advisable because this makes it difficult to take the measurements. Besides this, we advise you to wash your hair on the day of the experiment so that the electrode impedance can be easily increased to an acceptable level.
The experiment lasts for a maximum of 4 consecutive hours and you will receive a remuneration of € …. It is important to know that most of the subjects participating in similar experiments find it very interesting. You are introduced to a different type of research than usual and you can even watch your own brain in action online as well as the extent to which this activity is determined by opening and closing your eyes. At the end of the entire research, you may, if you so wish, be informed about the results obtained by means of a debriefing.

Yours sincerely,

Coordinator: Dr. …..Cubicus C….. Cognitive Psychology and Ergonomics Faculty of Behavioural Sciences University of Twente Tel: +31 (0)53 489…. email: …..
Research leader/Research assistant: …….Tel:….. email:……..

6.4 Informed Consent form

Below are examples of informed consent forms which can be modified to suit the relevant research.

6.4.1 Informed Consent for standard research

'I hereby declare that I have been informed in a manner which is clear to me about the nature and method of the research as described in the aforementioned information brochure 'XXXX'. My questions have been answered to my satisfaction. I agree of my own free will to participate in this research. I reserve the right to withdraw this consent without the need to give any reason and I am aware that I may withdraw from the experiment at any time. If my research results are to be used in scientific publications or made public in any other manner, then they will be made completely anonymous. My personal data will not be disclosed to third parties without my express permission. If I request further information about the research, now or in the future, I may contact …
If you have any complaints about this research, please direct them to the secretary of the Ethics Committee of the Faculty of Behavioural Sciences at the University of Twente, Drs. P.M. Groot P.O. Box 217, 7500 AE Enschede (NL), telephone: +31 (0)53 489 4591; email: p.m.groot@utwente.nl). Signed in duplicate:

…… *……*
Name subject *Signature*

I have provided explanatory notes about the research. I declare myself willing to answer to the best of my ability any questions which may still arise about the research.'

…… *……*
Name researcher *Signature*

6.4.2 Informed parental consent for research involving children

'I hereby declare that I have been informed in a manner which is clear to me about the nature and method of the research as described in the information brochure. My questions have been answered to my satisfaction.
I declare that I am authorized to sign for the participation of the child in the research concerned.
I agree voluntarily to the participation of the child in my care in this research. I reserve the right to withdraw this consent without the need to give any reason and I am aware that the child may withdraw from the experiment at any time. If the research results of the child in my care are to be used in scientific publications or made public in any other manner, then they will be made completely anonymous. The personal data of the child will not be disclosed to third parties without my express permission.
If I request further information about the research, now or in the future, I may contact the researcher Dr…. (tel: +31 (0)53 489…. or email …@utwente.nl; address: University of Twente, Cubicus, room, Enschede room…).
If you have any complaints about this research, please direct them to the secretary of the Ethics Committee of the Faculty of Behavioural Sciences at the University of Twente, Drs. P.M. Groot (P.O. Box 217, 7500 AE Enschede (NL), telephone: +31 (0)53 489 4591; email: p.m.groot@utwente.n).

Signed in duplicate on……..20..:
…… *Name subject* *Signature*
…… *Name parent/legal guardian* *Signature*

6.4.3 Passive Informed Consent, children

"You agree voluntarily to the participation of your child in this research. You reserve the right to withdraw this consent without the need to give any reason. Your child may withdraw from the research at any time. If the research results of your child are to be used in scientific publications or made public in any other manner, then they will be made completely anonymous. The personal data of your child will not be disclosed to third parties without your express permission. If you would like to have any further information about the research, now or in the future, you may contact Dr…. (telephone: +31 (0)53 489 xxxx; email: …@utwente.nl; postal address: Faculty of Behavioural Sciences, University of Twente, P.O. Box 217, 7500 AE, Enschede (NL)). For other questions and also for complaints about this research, please contact the secretary of the Ethics Committee of the Faculty of Behavioural Sciences of the University of Twente, Drs. P.M. Groot (P.O. Box 217, 7500 AE Enschede (NL), telephone: +31 (0)53 489 4591; email: p.m.groot@utwente.n). The headmaster/-mistress of your child's school agrees to the participation of your child in this research and offers full cooperation. If you have a formal objection to the participation of your child in this research, then you can make this known (no later than dd-mm-yyyy) to the head of the school (telephone, contact person N) or to the researcher at the University of Twente (Dr. NN, telephone: +31 (0)53 489xxxx; email: …@utwente.nl). You are not obliged to provide any reasons and your formal objection will be conceded without reserve.

6.4.4 Informed Consent CPE Department, pain stimuli

Informed Consent *The influence of emotion on the processing of pain stimuli*

I declare herewith that I have been informed both verbally and in writing and in a manner that is clear to me concerning the nature, method and purpose of this research. My questions have been answered to my satisfaction. The written information which accompanies this declaration has been handed to me.
I agree of my own free will to participate in this research. I reserve the right to withdraw this consent without the need to give any reason. In addition, I agree to the procedure to be followed in the event of accidental discoveries.

Subject number (to be filled in by the researcher responsible): …….
First name: ……. Surname: ……
Date of birth: ……..
Educational programme:
……
Medication: ……..
Contact details general practitioner: ……..
Date/time of experiment: ……..

Hand preference □ Right □ Left
Gender □ Man □ Woman
Comments: ……

Signature: ……..

Undersigned declares that the person named overleaf has been informed both in writing and orally about the research. He/she also declares that a premature withdrawal of the participation by the aforementioned person will not have any further consequences for him/her.

Name:
Position:
Signature: *Date:*