Protocol for assessing the ethical permissibility of proposed research in the Faculty of Electrical Engineering, Mathematics and Computer Science at the University of Twente

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Fast Reading Routine of the Protocol
- Appendix 5 contains the flowchart to assessment
- Appendix 6 gives the checklist for submitting a research proposal
- Chapter 4 summarises the standard research for the various departments (vakgroepen DACS, HMI, SCS)
- Chapter 3 describes the procedure to apply for an assessment.

1 Introduction
Over the past decades the global research community has become increasingly aware of the responsibility research institutes, as well as individual researchers, bear when carrying out research involving human subjects. This ethical awareness covers a variety of disciplines which nowadays also includes the technical disciplines such as Computer Science and Electrical Engineering.

Ethical permissibility of research has, to an increasing extent, become the subject of consideration within multiple research departments of universities worldwide. Accordingly, proof of research assessment may also be a requirement imposed by journal editors when reviewing submitted papers reporting about this kind of research.

As a result of these developments, the faculty of EEMCS (Electrical Engineering, Mathematics and Computer Science) at the University of Twente (UT), has set up a research protocol to assess the ethical issues related to research projects conducted within the faculty. Additionally, UT has established a faculty Ethics Committee (EC).

As the “the ethical issues related to research projects” may refer to a variety of items, it is necessary to define these issues. This is the main goal of this protocol. This protocol describes how to deal with them. It defines responsibilities to be assumed by individual researchers, including the faculty dean, and presents procedures to be followed when planning research. This document also describes which types of research assessments the Faculty EC will be limited to (e.g. medical vs. non-medical).

Note also that a restriction is made in terms of the scope of the EC and ethical issues regarding personal integrity are covered but issues of scientific integrity (plagiarism, data fraud and alike) are not.

Much of the newly proposed research within a research group is not completely novel by nature or set-up. From a methodical and ethical point of view, research proposals are often only a modification of research that has been previously carried out. In order to streamline the process of assessing the ethical permissibility of research proposals, the concept of “standard research” has been defined. Standard research refers, in contrast with (ethically) novel research, to research that has been carried out in the past on a more or less regular basis and thus may be assessed according to a fast track procedure. Such standard research is described in this protocol for each relevant research group. It is approved a-priori by the EC and can therefore follow a fast-track procedure, meaning, that under conditions the EC member in the department concerned may assess a proposal in stead of the full committee.

Chapter 2 of this protocol describes the classification of research types in more detail, along with the establishment and tasks of the EC, responsibility of the various stakeholders, and the procedure to review an EC decision. Chapter 3 describes the assessment procedure in full detail, and Chapter 4
describes the standard research that has already been identified for the various research groups and that can follow the fast-track procedure. This protocol concludes with a number of appendices, of which the last includes the important checklist to be used by a researcher considering to submit a research proposal to the EC.

The current EC protocol was initially derived from the protocol for the Faculty of Behavioural Sciences at the UT in the spring of 2012. Through the experience of the EC, the protocol has developed since then to accommodate the research typical of the faculty of EEMCS. It is envisaged that in the future this protocol will develop further, not only because of the specific nature of the EEMCS research, but also because of natural developments within the various research fields themselves.
2 Principles and overview.
This protocol addresses the research-associated ethical issues at the Faculty of Electrical Engineering, Mathematics and Computer Science (EEMCS) at the University of Twente. Ethical permissibility is judged on the possibility for harming human subjects as a result of the proposed research. These harms concern the personal integrity of a person, be it in his/her psychological, physical, or social interest. For this EC ethical permissibility does not include certain codes of conduct such as those concerning plagiarism, violation of intellectual property, data fraud, and alike. Medical research is excluded as well given that it must be submitted to a Medical Ethics Committee for legal reasons (see §3.1. and Appendix 4).

2.1 Scope of the protocol
All proposed research which involves interaction with, or data gathered from human subjects and which is carried out by the faculty must be submitted to the full EC or the relevant EC member in the case that it is considered standard research (see §4.1.) for an assessment of the ethical permissibility before conducting the study. Interaction with human subjects includes, but is not limited to, communication via electronic means such as e-mail, social networks, or other computer programs. Research which makes use of existing data, such as meta-analyses, does not need to be tested by the EC. For publication, however, it is important to comply with the rules and regulations concerning anonymity to uphold ethical values like privacy.

This protocol applies to research carried out by: ordinary/normal staff members, persons affiliated with a department in connection with the research (including guests, extraordinary [temporarily] professors, seconded staff), PhD students, postdocs, and masters students. Research that is carried out either entirely or in part on the premises of the faculty must be submitted for assessment. There is always a researcher employed by the faculty who bears primary responsibility for the research. Should the research be carried out by a student, 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 should also be submitted to the full EC or the EC member of the department (§ 4.1.). Research proposals involving subjects within the framework of education should also be submitted to the EC.

In the case of research performed jointly by different faculties of UT, one and only one of these faculties has to take responsibility for the research. Ethical permissibility of the research is then assessed by the ethical committee of the responsible faculty. In the case of research performed jointly by EEMCS and some organisation outside UT, ethical permissibility of the research is assessed by the EC of EEMCS regardless of whether an ethical committee of the other organisation(s) also assesses ethical permissibility. The exception to this rule occurs when a Medical Ethics Committee (MEC) assesses ethical permissibility, then the EC is not required for assessment.

2.2 The Faculty Ethics Committee (EC)
The Ethics Committee (EC) of the Faculty has been established by the Dean of the Faculty. The EC consists of a chairperson, a secretary and one member from each department (Vakgroep) that carries out ethically relevant research. The chairperson and the secretary are appointed by the Dean, as are the other EC members after nomination by the department chair of the department concerned. The Dean can add advisory members to the committee, for example an ethics researcher from the philosophy department. The EC meets a minimum of 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.
2.3 Tasks of the EC
The tasks of the EC are:
- to formulate and update the policy of the EC in detail and to keep the protocol up-to-date
- to approve the descriptions of the so-called “standard research” in the departments (see §2.4. below)
- to assess the ethical permissibility of research proposals which do not fall under the standard research or, – if they do fall under the standard, – do not meet the conditions to be assessed within the relevant department (see §2.4.).

2.4 Standard Research and Fast-Track procedure
Standard research refers to research that has been carried out previously in a department on a more or less regular basis and has been approved by the EC. Standard research is further described in this protocol (Chapter 4).
A research proposal falling under the umbrella of standard research for a department may be assessed in a fast track procedure. This means that the EC member of the department is authorized to make a positive assessment of the ethical permissibility of the research proposal under consideration. If the EC member of the department is him/herself involved in the proposed research, however, the proposal must be submitted to the full EC.
This procedure is designed to prohibit a researcher assessing his/her own proposal.

2.5 Significance of assessment
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, 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.
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 (Collective Labour Agreement Dutch Universities (CAO NU). In 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 (§2.6.) for review, the EC has the final word concerning the ethical permissibility of research, except in cases where an MEC is authorized.
The EC may, under exceptional circumstances or for special reasons, also terminate on-going research.

2.6 Request for reviewing decision
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, after his/her reconsideration, has found the proposed research to be permissible after all.
3 Procedure to apply for an assessment
All research proposals for which ethical permissibility is at stake (see Chapter 2) should be submitted in detail to the EC via the EC member of the relevant department. The EC member of the department where the research is conducted should subsequently report his/her initial findings to the EC. There is a checklist available (Appendix 6) that should be filled in and submitted along with the *information brochure* and the *informed consent forms* (§3.7. and Appendix 1). In some cases questions about obtaining *Personally Identifiable Information* will be asked (§3.9. and Appendix 2). The decision regarding ethical permissibility of the proposed research is taken by the full EC, or the EC member of the department in case of standard research (Chapter 4). In Appendix 5 the procedure to be followed is summarized in a concise flow chart. In the remainder of this chapter the general requirements and conditions to be considered when planning to submit a research proposal to the EC are described. In this phase of planning the researcher has established that the proposal to be submitted might be ethically disputable, meaning that possible harm to human subject’s personal integrity might be inflicted by the research, cf. the introductory section of Chapter 2.

3.1 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) (Appendix 4). Should this be the case, the EC of the Faculty is not authorized to make a decision about the ethical permissibility of the research. The research proposal is submitted to a recognized MEC in this case (for instance from the MST hospital in Enschede or from another institute which is involved in the research).

3.2 Selection of adult, competent subjects
In some cases participants are not aware of being subjects in an experiment, and even sometimes may never be aware of having been subjects in recordings of their behaviour. Examples are movement sensoring, video screening, search activities on the internet, hacking experiments, “theft” experiments etc. For these kinds of research proposals selection of subjects is not an item. Consequently, a researcher should describe the actions to be taken in the occurrence that these subjects unintentionally lose their anonymity in the course of experiment. Most notably, attention must be paid to: deception and debriefing (§3.10.), anonymity (§3.8.) and Personally Identifiable Information (§3.9).

In all other cases, in one way or another, participants, are approached to voluntarily act as human subjects in a trial. The following rules should then be adopted.

A subject is a healthy, adult (18 years or older) and mentally competent volunteer, who voluntarily (aka. Without coercion or force) participates in a trial and may receive a modest remuneration in return. Subjects are selected in one of the following manners:

a) 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 may be 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 not allowed to exceed a certain maximum remuneration 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 only still carries a negligible risk, for example cold stress), a maximum of € 20 per hour may be paid. 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 2013.

b) The researcher approaches an institution (school, company, etc.) regarding participation in the research prior to the beginning of the research project. The heads of these institutions in turn approach the residents/members/students about participation. This applies strictly to adult persons. For minors or legally incompetent subjects, see under the relevant department section in Chapter 4, that may make use of these subjects. Participants sign the informed consent (§3.7.) individually. When participation takes place in an institution (e.g. school, healthcare centre) or at the parents' home (on a voluntary basis), there is normally no financial remuneration, however, in these cases a small gift is given to the participant or the host institution for participation.

c) When subjects are individually interesting for a particular reason, for example because they have participated in earlier research or because certain data has already been collected from them, they may be approached individually to participate in (follow-up) research.

3.3 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 process that the following is made clear:

a. Whether there are any unpleasant procedures for which it is 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 accepted to participate in the research. Then subjects are entitled to some remuneration in the event that they withdraw from the research in this instance.

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 of harm than the average individual by participating. For example, people with metal clips for fMRI research, or pregnant women for experiments with alcohol, etc.

c. Whether material is used which for certain groups of people is offensive or inappropriate for any number of reasons including but not limited to religious beliefs. Examples include racial or explicit sexual photographs or films, use of alcohol and the like.

3.4 Screening of subjects
Should the research so require, subjects will be screened for common or less common qualities/disabilities. This could include eye examinations or other visual tests in the case of research on visual perception. Furthermore, certain inclusion or exclusion criteria can be employed, such as: gender, a particular age range, a particular range in IQ-score and/or other psychometric test scores. Subjects are not judged based on any of these qualities but are included or excluded depending on whether or not their personal variables match with other subjects.

3.5 Voluntariness of participation
Regardless of the selection method used, each subject is free at any moment and for any reason whatsoever to leave or break off the research. Also, for 24 hours after the research has ended 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, or be promised any remuneration which is higher than that stipulated above.

3.6 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. If there is any chance of this occurring, a clause
should be included in the informed consent which outlines a clear procedure to be followed in such a case. For instance that the subject is, or alternatively is not to be informed about such a result. 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.

3.7 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., associated with his/her involvement in the research. 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 on behalf of the subjects in question.

During the recruitment of subjects prior to conducting the research, the researcher should inform the subjects about what they can expect during the period in which the research is carried out. On the basis of this information, the subject is asked explicitly for permission to use the data obtained from him/her for the stated research purposes. After reading and understanding the information brochure pertaining to the research 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 into a single document. For standard examples of information brochures and informed consent forms see Appendix 1.

3.7.1 Minimum content of the information brochure

The information brochure should contain at least the following:

a. The name, the address, telephone number and e-mail address of the research leader.

b. The name, address, telephone number and e-mail 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 EC.

c. Details of the research procedure, activities to be carried out, potential for discomfort or risk etc. On the basis of this information, the subject should be able to make a reasonable estimate of his/her own expected discomfort, including its duration and further possible risks (even if these are negligible) involved in the research. This description should be written in clear and understandable language, free of jargon or unusual abbreviations.

d. All factors which could possibly influence the subject’s 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. (E.g. 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. Subjects may also end their
participation at any time and 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.

3.7.2 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 is aware 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 separate documents for these procedures and must also provide the necessary information (e.g. name and address of general practitioner) on each document. 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 in person. This happens 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.

3.7.3 Waiving signed informed consent forms
In some projects it is necessary to interview research participants about illegal activities they may have performed or may be involved in. Because identifying information is required on a consent form, potential participants may choose not to participate in such research projects which require the self-reporting of illegal activities if this information may later serve to incriminate them. Participants involved in illegal activities who do agree to sign the consent form may choose to limit their disclosure in the research, thus affecting the quality of the data. It is important to note that some form of informed consent is necessary in these cases in order to ensure high ethical standards of research.

In such cases the following procedure will be adopted: Prior to the interview, individuals who accepted the invitation to participate are read the contents of the informed consent form. They are given an information sheet with full details about the research. They are asked if they have any questions about the research and are then asked if they consent to the interview. The interviewer records on the interview sheet that the contents of the consent sheet has been read to the respondent and an opportunity has been provided for asking questions. Following these preliminaries, if informed consent has been obtained, the participant is interviewed. At no stage during the consent or interview process is the individual's name or identifying information requested. (This procedure is taken from: Lynne Robertsa & David Indermaura: Signed Consent Forms in Criminological Research: Protection for Researchers and Ethics Committees but a Threat to Research Participants?; Psychiatry, Psychology and Law 10(2):289-299, 2003. http://dx.doi.org/10.1375/pplt.2003.10.2.289

3.8 Anonymity
Data obtained from research is not disclosed to third parties in any way that would make it possible to link the results or other findings with a particular subject. Disclosure of data include, but is not limited to, publication in a journal, presentation at a conference, presentation in a colloquium, or discussion in
internal consultations. An exception to this is stated in 3.7.1 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 and 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 (e.g. 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, then explicit permission for this should be requested after the research has terminated. The use of such data is allowed only for those purposes 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.

3.9 Personally Identifiable Information (PII)
Some research enables the researcher to extract Personally Identifiable Information (PII) from the experiment though there is no purpose or need to have knowledge of this kind of information. To ensure that the researcher will maintain this PII in confidence, each researcher will sign a statement to keep any PII acquired from the experiment, intentionally or accidentally, confidential. Such a statement will be signed prior to the collection of data. A statement example of the kind is included in Appendix 2.

3.10 Deception and debriefing
Certain forms of deception of subjects are allowed. This is only permissible in cases when 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: intentionally providing inaccurate or incomplete information to the subject.
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.
Following research in which a subject has been deceived there is always a complete debriefing of the subject about the way in which (s)he was misled. If there is reason to expect temporary negative effects from being deceived, 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 that one can reasonably expect it would eliminate the temporary negative effects (e.g. 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.

3.11 Description of the research
Two descriptions of the research will be written up which will be used for:
(1) assessment by the EC or by the EC member concerned, and (2) providing information to the subjects in the form of an information brochure to support 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 reading and understanding the information brochure. In the event that information presented to subjects is misleading concerning the setup and purpose of the research, supplemental conditions will apply.
4 Standard Research within the Faculty
This chapter deals with the procedure to follow in the event of a fast-track procedure (see also §2.4.). Accordingly, this chapter addresses the concept of "standard research" and when it is applicable to a research proposal. Applicability of the label "standard research" differs depending on the research group/department. The second and major part of this chapter is filled with descriptions of the types of standard research in the various departments. These types of research are approved by the EC as being ethically permissible.

4.1 Procedure
As stated in this protocol, only research proposals which fall entirely within the specific types of research, as differentiated per department, can be defined as "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 the research proposal falls entirely within the category of standard research, 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 research proposal. The EC member checks the data and can then make either a positive or a negative decision about whether the research proposal is ethically permissible. The EC member informs the principal researcher and the EC secretary of his/her decision.

Research in which an EC member is him-/herself involved shall be submitted to the full EC. The department chair can submit a request for review to the Dean in the event of a negative decision regarding permissibility (§2.6.).

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, cf. Chapter 3) 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 e-mail) about the ethical permissibility of the research proposal and sends a copy thereof to the secretary. Only AFTER this has been completed can the research 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.

If no specific types of standard research have (as yet) been identified for a department and if there are no types of research present in other departments that completely resemble the proposed research, then the so-called fast-track procedure is not applicable.

4.2 Specific types of standard research per department
In this section, for each (relevant) department the "standard research" is described. In these descriptions the following items must be addressed (see also Chapter 3):

1. General description of the research in the department
2. Authorization EC: assessment of ethical permissibility by EC or by MEC:
3. Selection of adult, competent persons.
4. Voluntariness of participation:
5. Screening of subjects:
6. Accidental discoveries.
7. Informed consent
8. Anonymity
9. Personally Identifiable Information (PII)
10. Deception and debriefing
11. Recruitment of subjects
12. Specific type(s) of standard research
   a. ....
   b. ..... 

4.2.1 Department of Design and Analysis of Communication Systems (DACS)

General description of the research in the department
DACS carries out research on the design and analysis of communication systems. Examples of communication systems include, but are not limited to the Internet, mobile and embedded networks. Standard research within the DACS group thus pertains to research concerning either the design and/or analysis of such systems.

Authorization EC: assessment of ethical permissibility by EC or by MEC:
The standard research of DACS is not of a medical nature. In general, the questions are concerned with privacy aspects related to the analysis of network traces obtained from various networks. Thus, authorization for standard research within DACS falls to the EC and/or a member of the EC.

Selection of adult, competent persons.
DACS is never interested in the person behind the machines. Instead DACS is interested in the network traces made up of IP packets that have been generated by many machines. Consequently, the research at DACS focuses on networks rather than individuals. Examples of networks include campus networks, office networks, home networks etc. For this reason DACS does not select subjects per say, rather, DACS relies on networks of subjects and as a result there is no selection of persons as subjects.

Voluntariness of participation and screening of subjects:
Persons or their behaviour is not the subject of DACS research. Therefore there is no need to ask persons whether they would be willing to participate, nor to screen the subjects.

Accidental discoveries:
The kind of accidental discovery that could be discovered through the research at DACS pertains to the observance of malicious activity on a network. In case of accidental discovery of severe malicious network behaviour, the managers or CERT (Community Emergency Response Team) responsible for that particular network will be informed.

Anonymity:
Network traces contain data that is generated by networked computers that in turn may be generated by human beings. To preserve confidentiality, only control data (such as packet headers or flows) will be captured and stored. Only in rare cases, such as SPAM analysis, the contents of SPAM messages may be analysed. To ensure anonymity of data sources and destinations, stored traces will be anonymized (storing traces is needed to allow future researchers to validate the findings of our research).

DACS researchers (including students) who work with traces that potentially contain sensitive data are obliged to sign a Non Disclosure Agreement (NDA) before the start of their research. This NDA does not pertain to the finding of PII.

Specific type of standard research: analysis of network data
This kind of research is described in the text above.
4.2.2 Department Human Media Interaction (HMI)

General description of the research in the department
HMI carries out research on: human-computer interactions, human-human interactions, human-robot interactions, interface design, user experience, and the impact of technology on society. Most studies collect only behavioural data, but in some cases also peripheral (e.g. skin conductance, heart rate) and central neurophysiological (e.g. electroencephalogram) data are collected.

Authorization EC: assessment of ethical permissibility by EC or by MEC: The standard research of HMI poses questions which are not of a medical nature. In general, the questions are concerned with the normal interaction between healthy humans and an interface (e.g. human, computer or robot) or device. Thus, authorization for standard research within HMI falls to the EC and/or a member of the EC. In the event that peripheral or central neurophysiological data are collected then the approval of an MEC is sought

Selection of adult, competent persons. This is usually the case but in a few cases, the research may involve minors as subjects, namely:
1. When minors form a specific target group
2. When organizations (e.g. schools) are involved in which minors are specific stakeholders (an example of this is the research on cyber bullying). 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. In accordance with this protocol, subjects are informed that their participation is voluntary and they are allowed to decline or to withdraw from the research.

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

Accidental discoveries: On most studies accidental discoveries are not applicable in a medical sense. However, in the studies in which (neuro)physiological data are collected accidental discoveries can be made. In the chance that HMI researchers may uncover an accidental discovery they will follow the guidelines described in section 3.6.

Informed consent: Obtaining informed consent is usually applicable for this research group. When observation of an individual is involved (whether electronically or not) and when 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. The texts are anonymized in the research report. An informed consent form waiver may be issued only when the informed consent form might otherwise jeopardise the research, for example when interviewing potential offenders.

Anonymity: Research data of persons is made anonymous at the earliest possible stage right up until the research report. The only exceptions to this are when the person concerned has given their expressed permission to de-anonymize their information. 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 may occur in a number of studies in the sense that the purpose of the research is concealed in order to prevent full knowledge of the research from influencing the behaviour of the subjects. In these instances debriefing takes place afterwards. Debriefing is completed by a trained individual with experience in this area.

Recruitment of subjects: Risks such as those listed under a, b and c of section 3.3. can be applicable. Subjects will be informed if these risks are greater than those found in a normal work, learning or home situation.

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: user experience, usability, emotions, cognitions, and behaviour in social interactions (e.g. online). If questions are asked about emotional or sensitive topics (such as cyber bullying), 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 settings involving virtual or real human-human, human-computer or human-robot interaction, either alone or together with a number of other people at the same time. Their behaviour during interaction is measured by behavioural and/or (neuro)physiological assessments. Subjects also sometimes have to make choices, pass judgement or perform short tasks. 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. Audio and video recordings are not made available to third parties without informed consent. Recordings in which subjects are identifiable are carefully stored for 5 years and are destroyed when no longer needed for the purposes of the research.

Specific type of standard research: Laboratory research with deception
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 (i.e. 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 2 hours. No physical discomfort or health and safety risks are involved. Stimuli which are not subliminally presented are often (1) online/offline environments, texts, images, film fragments which induce emotions/moods (mood/emotion manipulation), online reactions to information presented via web sites or other ICT means, and/or (2) behaviour of an actor confederate or robot.

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 given that it is specifically developed to arouse particular positive or negative emotions. Accordingly, it is reasonable to expect that it will arouse particular emotions. Given this, care will be taken to debrief the subject after the experiment.

4.2.3 Department of Services, Cybersecurity & Safety (SCS) / Section: Services

General description of the research in the department
The mission of the section Services of SCS is to develop and study techniques for the determination of requirements and the design of architectures of information systems. In information systems research, very often there is a link with the environment (e.g. company/organisation) in which an information system is used. Therefore, many research projects involve studying this environment, e.g. via case study research, action research, or conducting surveys. The Section often studies one particular class of information systems, namely those employed by healthcare providers in direct contact with patients.

Authorization EC: assessment of ethical permissibility by EC or by MEC: due to the focus of the section Services on the healthcare domain as the application area for its research, researchers in the Section carefully consider the criteria described in Appendix 4. Much healthcare-related research of the section falls under the responsibility of an MEC due to the primary selection criterion described in Appendix 4: a hospital (or similar institution) is involved. If no hospital (or similar institution) is involved, research can still be of the type that the research must be assessed by an MEC. The current section describes standard research of the Services Section in which no hospital or similar institution is involved, that is non-medical in nature, and that involves either negligible risk or only privacy violation risks to research subjects, both to be submitted to the EC.

Selection of adult, competent persons. Standard research of the Services Section is limited to adult, competent persons.

Voluntariness of participation: Standard research of Services only involves voluntary participants.

Screening of subjects: The only screening in standard research of Services is research subject selection based on age (due to focus on healthcare research for elderly).

Accidental discoveries: Standard research of Services is not likely to lead to accidental discoveries.

Informed consent: Standard research of the Services Section involves full informed consent and complies with the minimum content guidelines of Section 3.7.1.

Anonymity: in the Services standard research, any personally identifiable data is kept confidential

Deception and debriefing: Standard research of Services does not involve deception.

Recruitment of subjects: in standard research of Services, 3.3. does not apply.
Specific type of standard research: (multiple) case study research at companies. In this type of standard research, researchers interview subjects in their capacity as employees of one or more companies or other organisations. The goal is to observe this organisation (the actions it takes, the documents it produces) and/or its employees (their behaviour and opinions), but not to influence or change this. Data is collected in the form of: filled-in questionnaires, audio recordings of interviews, or researcher-generated notes containing verbatim quotes of statements made by the subjects. In the case of action research (a variant of case study research in which researchers do try to influence the organisation under study), next to research ethics also professional ethics come into play, but this is not governed by the EEMCS Ethics Committee.

Specific type of standard research: laboratory experiment. In this type of research, competent adults voluntarily and knowingly participate in an experiment in which their performance on some task is observed. An example is an experiment in which students apply a new information systems modelling technique to a case. The resulting models and/or their behaviour while applying the technique is recorded. For this type of research to be standard, if the subjects are students of UT, there is no remuneration in the form of ECTS credits, waivers for obligations in courses, or any other link to student assessment in courses.

4.2.4 Department of Services, Cybersecurity & Safety (SCS) / Section: Cybersecurity

General description of the research in the department
The Section Cybersecurity of SCS carries out research on the relationship between ICT and crime or, ICT and disorder (e.g. graffiti, littering, loitering)

Authorization EC: assessment of ethical permissibility by EC or by MEC: The standard research of the Section Cybersecurity 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) situations with a risk of crime or disorder. Thus, authorization for standard research within the Section Cybersecurity falls to the EC and/or a member of the EC.

Selection of adult, competent persons. This is usually the case but in a few cases, the research may involve minors as subjects. The use of minors as subjects occurs only in the following cases:
1. When minors form a specific target group for the crime or disorder to be investigated (e.g. truancy),
2. When organizations (e.g. schools) are involved in which minors are specific stakeholders (an example of this is the research on cyber bullying). 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. In accordance with this protocol, subjects are informed that their participation is voluntary and they are allowed to decline or to withdraw from the research.

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

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

Informed consent: Obtaining informed consent is usually applicable for this research group. When observation of an individual is involved (whether electronically or not) and when 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. The texts are anonymized in the research report. An informed consent form waiver may be issued only when the informed consent form might otherwise jeopardise the research, for example when interviewing potential offenders.

**Anonymity:** Research data of persons is made anonymous at the earliest possible stage right up until the research report. The only exceptions to this are when the person concerned has given their expressed permission to de-anonymize their information. 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 may occur in a number of studies in the sense that the purpose of the research is concealed in order to prevent full knowledge of the research from influencing the behaviour of the subjects. In these instances debriefing takes place afterwards. Debriefing is completed by a trained individual with experience in this area.

**Recruitment of subjects:** Risks such as those listed under a and b of section 3.3 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. Subjects will be informed if these risks are greater than those found in a normal work, learning or home situation.

**Specific type of standard research: Questionnaire-based research (field research)**
In this type of research, respondents individually fill in answers, in writing or electronically, to questions about themselves, their environment or others in their environment (e.g. friends, partner, fellow students, etc.). This may be done on an individual basis, as a group or in a class. Usually no observation of behaviour takes place and no physiological measurements are taken.

In these instances 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 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: social status, personality traits, attitudes, stereotypes, opinions and preferences; experiences (e.g. as a result of victimisation); emotions, cognitions, and behaviour in social interactions (e.g. online); autobiographical memories (e.g. the last time that the subject was victimised); etc. If questions are asked about emotional or sensitive topics (such as experiences of victimisation, crime, disorder, 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 (examples of stimuli are listed below), 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. Sometimes, subjects also 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 are 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 without informed consent. Recordings in which
subjects are identifiable are carefully stored for 5 years and are destroyed when no longer needed for the purposes of the research.

For this type of 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) online/offline environments, texts, images, film fragments which induce emotions/moods (i.e. mood/emotion manipulation), online reactions to information presented via web sites or other ICT means, 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 (e.g. ‘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, meaning, it is specifically developed to arouse particular positive or negative emotions. Consequently, it is reasonable to expect that it will arouse particular emotions.

4.2.5 Department of Services, Cybersecurity & Safety (SCS) / Section: Safety

General description of the research in the department
The Section Safety of SCS carries out research in the domains of medical imaging and biometric pattern recognition. The former is not relevant in this context because the medical data is acquired via other groups or institutions, or taken from datasets, and is approved to be used for the research purposes of Section Safety. The research on biometric pattern recognition (BPR) involves the use of subjects for collecting biometric databases and for experiments in which biometric systems are used. In both cases biometric data is acquired via sensors that include cameras and/or fingerprint sensors. Subjects can therefore be exposed to low-energy infra-red illumination. Non-invasive markers may be applied to the subjects. Subjects may be asked to play a certain role, such as robbing a store, only for the purpose of acquiring biometric data.

Authorization EC: assessment of ethical permissibility by EC or by MEC:
The standard BPR research of the Section Safety poses questions and collects information pertaining to biometric markers, both of 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 in the home environment, at entrance gates or behind a computer.

Selection of adult, competent persons.
This is usually the case but in a few cases, the research may involve minors as subjects, namely when biometric data of minors is collected.
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 it is necessary to guarantee that the random sample is representative of the research population.

Accidental discoveries:
On most studies accidental discoveries are not applicable in a medical sense. However, in some studies medical information can be inferred from biometric data. In case researchers of the Section Safety suspect an accidental discovery they will follow the guidelines described in section 3.6.

Informed consent:
This is usually applicable. Subjects are specifically asked to consent to the anonymous use of their biometric data for research purposes. If applicable, they are asked to consent to the inclusion of their biometric data in a database that will be made publically available, after having been informed about the conditions of use of that database by third parties. They are also asked to consent to the use of the anonymous presentation of their data in publications.

Anonymity:
Research data of persons is made anonymous at the earliest possible stage, and certainly in research reports, unless the person concerned has given express permission not to do so.

Deception and debriefing:
Deception does not play a role in BPR research.

Recruitment of subjects:
Risks such as those listed under a, b and c of section 3.3. are not applicable. It might be that providing biometric data is somewhat inconvenient because of the number of repeated trials. Subjects will be informed about this.

Specific type of standard research:
Subjects are asked to provide their biometric data, e.g. by looking into a camera, by putting fingers or hands on a sensor. When they take part in data collection, this may happen multiple times in a number of sessions.
Appendix 1 Examples of the Information Brochure and Informed Consent Form
(see section 3.7.)

Introduction
Every participant in a research trial receives an information brochure and an informed consent form to be signed. The purpose of this is as follows:
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 is an example of an information brochures that cover research where accidental discoveries are possible (cognitive ergonomics). Below this are examples of informed consent forms that cover the following topics: research where parent permission is required in the case of research involving children (developmental psychology); and, research where passive informed consent applies (developmental psychology). The content and the layout can be modified to suit the relevant research and research department.

1. Sample Information Brochure
   (CPE department (Behavioural Sciences))

   Enschede, date.....

   Information brochure Department DD
   (accidental discoveries)

   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-yyyy, in room xxx of the xxx building. 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. Moreover, 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.
   First, 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.
   Second, 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.
   Third, 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.
Fourth, 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.
Fifth, 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.
Finally, 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. NN…Department xx, xx building, Faculty of BS University of Twente Tel: +31 (0)53 489…. email: …..
Research leader/Research assistant: ……..Tel:…… email:…………..

2. Informed Consent forms

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

2.1. 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 Electrical Engineering, Mathematics and Computer Science at the University of Twente, dr. ir. J.F.C. Verberne, P.O. Box 217, 7500 AE Enschede (NL), telephone: +31 (0)53 489 3700; email: j.f.c.verberne@utwente.nl). Signed in duplicate:
……………………………
Name subject
Signature
……………………………
Name researcher
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.'
2.2. 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, Building, 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 Electrical Engineering, Mathematics and Computer Science at the University of Twente, dr. ir. J.F.C. Verberne, P.O. Box 217, 7500 AE Enschede (NL), telephone: +31 (0)53 489 3700; email: j.f.c.verberne@utwente.nl).

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

2.3. 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…NN. (telephone: +31 (0)53 489 xxxx; email: …@utwente.nl; postal address: Faculty of Electrical Engineering, Mathematics and Computer Science at the , NN, 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 Electrical Engineering, Mathematics and Computer Science at the University of Twente, dr. ir. J.F.C. Verberne, P.O. Box 217, 7500 AE Enschede (NL), telephone: +31 (0)53 489 3700; email: j.f.c.verberne@utwente.nl). 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.

2.4 Informed Consent Department XXX,
Informed Consent project PPP

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:
Appendix 2 Personally Identifiable Information (PII)
(see §3.9)

Example of a statement concerning the use of Personally Identifiable Information (PII),
Department SCS/Cybersecurity, Cyber-Crime Science Course

STATEMENT CONCERNING THE USE OF PII

Personally Identifiable Information (PII) is information that can be used to uniquely identify, contact, or locate a single person, household, enterprise or institution or can be used with other sources to uniquely identify a single person, household, enterprise or institution.

The undersigned
(name)………………………………………………
(student number)……………………………

hereby undertakes to carry out a project in the context of the University of Twente Cyber-crime Science course (CCS), in accordance with the following conditions:

1. He/she undertakes to keep confidential any PII which comes to his/her knowledge during the work on these projects.

2. He/she undertakes not to distribute any PII to others without written permission of the lecturers of the CCS course.

3. He/she undertakes to use the PII for purely scientific (i.e. non-commercial) research only.

4. This statement shall remain valid, even after conclusion of the work specified.

(signature) ………………………………………
(e-mail address) ……………………………@…………………………………………
(date)……………………………………..
(place)…………………………………………
Appendix 3 EC members and contact information

Contact Information
Ethics Committee, Faculty of EEMCS,
University of Twente
PO Box 217
7500 AE Enschede (NL)

Tel: +31(0)53.4894602  email: BFD_EWI@ewi.utwente.nl
Fax: +31(0)53.4893114  website: http://www.utwente.nl/en/education/eemcs/

List of members of the EC:
dr. ir. A. Pras (chairman)  dr. ir. H.J.A. op den Akker
(Department DACS)  (Department HMI)

Prof. dr. R.J. Wieringa
(Department SCS)

Ethical Advisor  dr.ir. J.F.C. Verberne (secretary)
dr. A.L. van Wynsbergh  Managing Director (EEMCS)
(Philosophy Department, Faculty of Behavioural Sciences)
Appendix 4. Criteria for Medical-Ethical Assessment
(See §3.1.)

In this Appendix the general criteria are mentioned concerning when the research at the Faculty must be tested by a nationally recognized Medical Ethics Committee (MEC), and when assessment by the local Ethics Committee (EC) of the faculty is sufficient. The *Wet medisch-wetenschappelijk onderzoek met mensen (WMO, 2006)* gives general rules. In this (EEMCS) protocol, the interpretation of the ethical committee of the Faculty of Behavioural Science (BS) at UT is followed. Moreover, here (EEMCS) only the global (primary) selection criteria are adopted; detailed secondary and tertiary criteria as mentioned in the BS protocol are left out here, as the general nature of the EEMCS research is in most cases far from the medical questions addressed in these criteria. In case of doubt they are available in the administration of the Faculty EC.

**Medical research**

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

1. A hospital is involved in the research, 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 negligible or a non-negligible risk for the subject.

For non-medical research, the main criterion with regard to the ethical permissibility is the risk to the subject. If medical equipment is used in the research, then the EC may seek advice from an MEC regarding the risks connected with such equipment.

So, 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 equipment**

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.
Appendix 5 Flowchart to assessment
(See Chapter 3)

Principal investigator submits research proposal with information to EC member of the department

The proposal is registered as standard research (fast-track procedure)

EC member decides that the research falls under standard research and is ethically permissible and informs researcher and secretary

EC member questions whether this is standard research and requests more information; execution may not yet begin

EC decides that the proposal does not fall under standard research

EC member decides that the proposal does not fall under standard research and submits proposal to full EC

EC decides that the research is of a medical nature. EC refers to MEC. Execution may not yet begin

EC is uncertain. EC requests more information. Execution may not yet begin

EC decides that the research is not ethically permissible. Considers requesting second review by dept. chair

EC decides that the research is ethically permissible. Execution may begin. Secretary informs researcher
Appendix 6. Checklist for submitting a research proposal to the Ethics Committee
(See Chapter 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 a research proposal

1. General

1. Title of the project:
2. Principal researcher (with doctoral research also a professor):
3. Researchers/research assistants (PhD students, 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):

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. Is the research proposal to be considered as medical research (Also see Appendix 4)
   - Yes
   - No
   - Uncertain
   - Explanatory notes:

3. Are adult, competent subjects selected? (§3.2)
   - 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? (§3.2)
   - 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? (§3.4)
   - 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? (§3.6 and Appendix 4)
   - 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? (§3.2, §3.3, §3.7, §3.8)
   - 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 (§3.8)?
   - 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) (§3.10)?
   - 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? (§3.5)
    - 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. 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 under one of the descriptions of standard research as set out in the described standard research of the department? (Chapter 4)
    - 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.