PROCEDURE FOR THE ETHICAL REVIEW OF RESEARCH AT THE UNIVERSITY OF AMSTERDAM'S FACULTY OF HUMANITIES

Laid down by the Dean on 17 January 2012

Ethics Committee
Faculty of Humanities
University of Amsterdam

CONTENTS

The structure of this document and much of its literal wording were adopted with permission from the comparable document published by the Psychology Department.

1. The Ethics Committee of the University of Amsterdam's Faculty of Humanities

1. All research involving human participants conducted at the Faculty of Humanities must be submitted to the Ethics Committee (EC) in advance.[1] This applies to research conducted by staff members and doctoral candidates, postdocs and students. All research fully or partially conducted within Faculty of Humanities facilities must be submitted to the EC. A researcher employed or admitted by the Faculty of Humanities will always have primary responsibility for the research. If the research is being conducted by a student, intern or temporary worker, responsibility for their work must be allocated to a Faculty of Humanities staff member. Researchers that also have appointments at other institutions will submit their research to the institution at which the researcher responsible for overseeing the research has the most significant appointment, and in any event to the institution at which the research is being conducted. Research being conducted by a Faculty of Humanities researcher in another location (such as a school, business or institution) must also be submitted to the EC. Research being conducted as part of a research practice must also be submitted to the EC: please note that all applications for 'non-standard' research must be submitted on time.

2. The EC has drawn up guidelines on carrying out research, and issues binding decisions on permissibility. The Faculty of Humanities is not responsible for research that has not been submitted to the EC in advance. This means any such research will be carried out at the researcher's own risk. Societal developments or new experiences in the research field can result in regulatory changes and spark debates on the permissibility of research. The EC always has the final say regarding the permissibility of research, and may (in exceptional cases) revoke its approval or provisional approval of an ongoing research project.

3. In order to minimise delays to research projects, the EC strives to ensure a smooth review procedure, short lines of communication and clear procedures. The EC strives to minimise any additional administrative workloads for researchers. To this end, the EC has defined various types of 'standard' research. This concerns forms of research that have been conducted at the Faculty of Humanities for many years and are commonly practised around the world, whereby the differences between individual research projects need not have any consequences in terms of the ethical review. This includes research projects in which the stimulus material, questionnaire type or experiment type differs only marginally from previous research projects approved by the EC. If the entire research project can be categorised under such a standard, a *fast-track application procedure* will apply. This procedure consists of filling out a **checklist** (see Chapter 4) and submitting the *information brochure* and *informed consent forms* for the research project (see section A). The EC (in practice: the expert member or members responsible for the relevant discipline) will then check this information (outside of the EC meeting) and approve the research. In cases where the research cannot be fully categorised under the standard, or does not come within the standard at all, the researcher will have to provide the EC with detailed information on the research project. Here too, the procedure will include filling out of the checklist and submission of the **information brochure** and **informed consent forms** needed for the research project (see section A). These

[1] Research involving the use of existing data, such as meta-analyses, will not require a review by the EC. However, all publications must be in accordance with the relevant regulations on anonymity, etc.

documents must be supplemented with information on aspects of the research project that differ from standard research, and the information required by the EC in order to reach a decision on approval. The EC may initially issue a provisional approval. Definitive approval can only be issued at an official meeting attended by all EC members (see 4).

4. The EC consists of a chairperson, various members with specific areas of expertise covering all involved disciplines (see Appendix 2), and the professor of Ethics from the Philosophy Department.[2] The committee secretary is provided by the Faculty Office's Research Department. The EC will meet as often as necessary on an ad-hoc basis, in order to minimise disruption of the research (the meeting schedule is published on the EC website, which can be accessed via www.hum.uva.nl/onderzoek). Over the course of these meetings, the EC's policies will be further elaborated, standard descriptions will be supplemented or adjusted and specific research projects submitted to the EC will be discussed (see 3).

5. Research projects that are submitted to the EC in their entirety (and are not eligible for a fast-track procedure) will be discussed at the subsequent scheduled meeting, or sooner if possible and justified by urgent reasons. This means decisions regarding the approval or disapproval of research projects will always be issued within two months (unless the submitting parties are requested to provide further information and fail to do so; in this case, the decision will be issued at a considerably later date).

[2] The current composition of the EC is published on the EC website, which can be accessed via www.hum.uva.nl/onderzoek.

2. Procedure for submitting a project to the Ethics Committee

1. In order to accurately review a research project, the EC must know within what discipline the relevant type of research will be carried out. In many cases, researchers working in this discipline will have extensive experience in carrying out these types of research; research that has never been carried out in a specific discipline will require the EC's special attention. This means the first step will be to determine under what discipline the research resides.

2. Separate applications must be submitted for each clearly distinguishable aspect of the project. Different aspects may be allocated to different disciplines if necessary. The responsible researcher is basically free to determine which aspects of the research project will require a separate application. For example, separate applications can be submitted for a) each individual assignment or internship carried out by a student, b) each component of a doctoral research project that could culminate in an individual publication or chapter, or c) each aspect of the research project that requires a different experimental approach.

3. Formulate a written description of the research project, which will be submitted to the participants. This **information brochure** must clearly inform the participants of the amount and nature of effort, risk or discomfort the research will involve. The brochure must also contain other stipulations (see informed consent) regarding reimbursement, the voluntary nature of the participation, screening, insurance, anonymity, etc. Prepare an **informed consent form** that participants can sign if they agree to participate after having read the information brochure. Additional stipulations apply to cases where participants must be provided with misleading information for the purposes of the research.

4. Fill out the **checklist** (see Chapter 4). Start by filling out the general section, and then fill out the section on the research group that will be carrying out the research project. Under no circumstances should the research project be allocated to a specific research group with the aim of increasing the likelihood of approval (see 1).

5. Naturally, all checklist questions must be answered truthfully. Researchers are explicitly requested to answer these questions in the *spirit* of the text, rather than its literal wording. In other words, any ambiguous formulations should not be interpreted to one's own advantage. In the case of even the slightest doubt, the researcher must always fill in the answer 'not sure'. This applies especially to the question on whether your research project falls within a specific standard category. Naturally, it would be impossible to describe all possible versions of a specific research project, which means the featured descriptions are not exhaustive. You should only classify your research project as a standard research project if it meets *all* preconditions outlined in the description. Here too, you must fill in 'not sure' if there is even the slightest doubt.

6. When the checklist has been completed, it will be clear whether your research project is eligible for a *fast-track procedure* at the EC or must be *submitted in its entirety.* In some cases, a research project may not fall within the jurisdiction of the Faculty of Humanities' EC because it is subject to the *Medical Research (Human Subjects) Act.* In the latter case, the research project must be assessed by an accredited Medical Ethics Review Board,

such as the board at our Faculty of Medicine (AMC-UvA). Also see section Al in the subsequent chapter and Appendix 1.

7. In the case of a *fast-track procedure*, it will suffice to submit the checklist and accompanying paperwork (informed consent, information brochure for participants) to the EC's secretary. After having confirmed receipt of the documents, the secretary will forward your application to one (in some cases two) of the EC members, after which you will receive notification regarding the approval or disapproval of your application. *Only then* can the research project be initiated. The EC member may also request – either directly or through the secretary - that you provide further information. The research project may not be initiated until this information has been provided. In other cases, the EC member may decide over the course of the fast-track procedure (because he/she has identified non-standard aspects, has doubts, or for other reasons) that the research project will have to be submitted to the entire EC commission; you will then be duly notified by the secretary and requested to follow the steps described under point 8.

8. In the event that the research project must be *submitted to the EC in its entirety*, you will be required to send a detailed description of the research project and all other relevant documents to the EC's secretary. At minimum, this description must outline the areas in which the research project differs from a 'standard' research project. If the research project is regarded as standard in a discipline other than the one under which it has been classified, a reference to the relevant description will suffice. The EC member with expertise in the relevant field can then issue an initial judgement as to whether the research project can be initiated before having been discussed at the plenary EC meeting. In this case, the research project may be provisionally and conditionally initiated (i.e., the research project may be initiated, but can still be terminated by the EC at any point). The secretary will then notify the entire EC of the proposal; the EC may then decide to hold an ad-hoc meeting, or discuss the matter at the next scheduled EC meeting. Once the EC has deliberated on the research project, (definitive) approval can be granted and the project may be initiated. If no approval is issued, this decision will be motivated by the EC, who will also offer suggestions on adjusting the research project. The EC may also decide that it is not authorised to issue a decision on the research project. This generally occurs in cases where the EC decides that the research project is subject to the Medical Research (Human Subjects) Act, and must be assessed by a Medical Ethics Review Board.

3. Standardised research at the Faculty of Humanities

A research project may be categorised as standardised research by the Faculty of Humanities. If so, the project is eligible for the fast-track procedure (see Chapter 2).

Research will only be classified as standardised if it meets all the preconditions set out in section A, and the preconditions for standard research types for the relevant research group (section B).

A: Stipulations governing all research projects

A1. Review by the EC or METC

The first step consists of determining whether the research project requires assessment by an accredited Medical Ethics Review Board (METC). If this is the case, the Faculty of Humanities' EC has no jurisdiction to approve the research project, which must then be submitted to an accredited METC for approval (such as the METC of the AMC-UvA or another institution involved in the research project). The criteria for determining whether a research project is to be assessed by the EC or an METC are listed in Appendix 1, which also features a quick reference flow chart. The relevant regulations and guidelines are set out in the Medical Research (Human Subjects) Act (*Wet medisch-wetenschappelijk onderzoek met mensen*, or WMO). There is also a Central Committee on Research Involving Human Subjects (*Centrale Commisie Mensgebonden Onderzoek*, or CCMO) (see http://www.ccmo-online.nl). Research is subject to the WMO if it meets the following two preconditions:

1. the research is of a medical nature, and
2. human participants will undergo some form of treatment or be required to comply with a certain form of behaviour.

A2. Selecting adult, mentally competent participants

Participants must be healthy, mentally competent adults (18 years and over) that are taking part voluntarily without receiving disproportionate reimbursement. Participants are selected through one of the following procedures:

a) The participant is recruited through an advertisement in a newspaper or a poster at a UvA faculty or other institution, educational or otherwise. Participants can also be recruited from companies or organisations that employ groups relevant to the research project, such as 'managers' or 'cultural minorities'. Participation in the research is subject to reimbursement. The standard reimbursement is €6 per hour, although this amount can be higher depending on the amount of discomfort involved in participation. However, researchers may not exceed certain maximum amounts in order to persuade participants to take part in an experiment they would not be participating in otherwise. For example: the reimbursement for completing questionnaires or participating in research projects in the category 'behavioural tasks' (either individually or in a group) may not exceed €10 per hour. Reimbursement for physiological measurements involving an extremely low level of discomfort (such as heart rate, EEG, fMRI) will not exceed €15 per hour. The reimbursement for research involving a higher level of discomfort (but a negligible risk, such as cold stress) will not exceed €20 per hour. In some cases, reimbursement will consist of a lecture for the company or organisation from which the participants were recruited, rather than individual reimbursement. The amounts listed above are based on the 2011 average price level and should be indexed accordingly. Children will not receive monetary reimbursement.
b) Participants are recruited by means of newspaper advertisements or posters at a UvA faculty or other institution, educational or otherwise, targeting individuals with a specific

characteristic or experience that is common but cannot be categorised as ‘pathological’; for example, an advertisement may target ‘Spanish-speaking Dutch learners’, ‘monolingual Portuguese-speaking Brazilians’, ‘deaf people’, ‘babies with Dutch language input from the Brabant region’, or ‘dyslectics’. Participation is remunerated, with reimbursement levels depending on the amount of discomfort involved in the research project (see point a).

c) The researcher will contact an institutional environment (school, care institution, company, etc), which will then ask its residents/members/students to participate. All participants must be adults (for non-adult or mentally incompetent participants, see section B and Appendix 1). Participants must individually sign the informed consent form (see point A6), although all participants may sign the same form in some cases. If the research is to take place in an institutional environment (such as a school, care centre or in the home of elderly participants (on a voluntary basis), there will generally be no financial reimbursement. In such cases, however, a small gift will generally be presented to the participant or institution.

d) Participants can be of individual interest for various reasons. For example, they may have participated in a previous experiment, or the researchers may already have data on them. Based on this background, a participant may be individually recruited for participation in a research project or follow-up research project. Examples:
   i. A participant previously took part in an fMRI experiment, during which an MRI scan was made. This scan has been further processed to create a segmented MRI brain image. Creating such a segmented image takes a great deal of time, and MRI scans are costly (a good scan will require around 3 shorter MRI scans which take 10 minutes each). Having such a participant take part in multiple experiments can thus help save time and money. The participant may be requested to take part in a follow-up research project.
   ii. A participant is deemed to be of interest on the basis of scores from previous testing. The new researcher will not be provided with the individual scores for each participant. The researcher may ask his/her predecessor for participants with low and high test scores. The previous researcher will then ask these subjects whether they wish to participate in an experiment. The new researcher will receive a list of participants with low and high test scores, but will not be aware of each subject’s score. Each participant will also be assigned a number. Once the measurements have been carried out, the new researcher will be provided with a key to decipher which numbers correspond with the low-scoring group and which ones with the high-scoring group.

A3. The voluntary nature of participation

Regardless of the selection method, all participants are free to leave or discontinue the experiment at any moment and for any reason, without any adverse effects on their study curriculum, etc. The participant is also free to decide that his/her data should not be included in the research project after the experiment has been completed, but within a period of 24 hours. Persons recruited on an individual or group basis may not be pressured in any way (including peer pressure) to take part, or enticed with the offer of reimbursement exceeding the amounts mentioned above.

A4. Screening participants

Where necessary for the purposes of the research project, participants may be screened for common or rare disorders. This could include hearing tests in the case of research on speech

perception or questionnaires on neurological or psychiatric disorders in the case of an EEG recording, or claustrophobia in the case of fMRI research. In the case of fMRI research, all participants will be subjected to special screening procedures to minimise the risks associated with such experiments (see the relevant section). Researchers may also apply certain inclusion/exclusion criteria, such as a specific age or language proficiency score spread. The application of such criteria can serve various purposes, such as matching with other participants.

A5. Incidental findings

Some research methods may yield incidental findings that can be of interest to the participant. This could include cardiac dysrhythmia discovered during an ECG, irregular EEG results (epilepsy) or irregularities on an fMRI scan. Where possible, the informed consent form should feature a guideline on the appropriate follow-up procedure in such cases. When taking part in such research projects, the participant must specify the name and address of his/her doctor or general medical practice for notification purposes in the event that the experiment yields relevant medical information. If the participant does not have a doctor, he/she must consent to the fact that the student doctor (or in some cases the occupational physician) will be informed. The participant must consent to this procedure by signing a separate clause in the informed consent form.

A6. Informed consent

Informed consent means the participant consents to the research, and grants this consent on the basis of accurate and comprehensive information on the expected procedures, discomfort, risks, duration, purpose, etc. Researchers must provide all participants with an informed consent form (see below for the procedure for participants incapable of giving informed consent, such as children).

Prior to the actual experiment, during the recruitment of participants, the researcher will inform the participants as to what they can expect during the experiment. After having taken cognisance of this information, the participants will then be requested to grant express permission for the use of their data in the research project. After having taken cognisance of the *information brochure* relevant to the research project, the participant will then sign an *informed consent form* before the start of the experiment. The information brochure and informed consent form may be two separate documents, or compiled in a single document. For standard examples of an information brochure and informed consent form, see Appendix 4.

At minimum, the *information brochure* must include:

a. The name, address, phone number and email address of the research project leader, who can be contacted by the participant if he/she has any further questions.
b. The name, address, phone number and email address of the official EC secretary, who can be contacted by the participant if he/she has any complaints.
c. The research procedure, outlining all actions to be carried out, etc. This information should offer the participant a clear picture of the amount of discomfort he/she can expect, the duration of the experiment and the risks (even if these are negligible) involved. This description must be worded in easily understandable language, without any use of jargon or uncommon abbreviations.
d. All factors that could have a negative impact on the subject's willingness to participate, such as risks, discomforts or adverse effects.
e. The reimbursement for participation in the research, and the conditions under which this reimbursement will be provided. If any professional services (such as treatment or

education) are being offered in return for participation, the researcher must clearly explain the nature of these services as well as the involved risks, obligations and restrictions to the participant.

f. The various types of people advised not to take part in the research, due to increased susceptibility to risks or discomforts. This could include people suffering from claustrophobia in the case of fMRI experiments, people prone to fainting in the case of emotional stress experiments, pregnant women in the case of experiments involving substances such as alcohol, etc. (this does not discharge the researchers of their responsibility to carry out the screening procedures required for various types of research, see A4).

g. The purpose of the research. If the purpose of the research cannot be announced in advance in view of the questions, the participant must be provided with an explanation at the earliest possible opportunity after the research has ended. This will include a debriefing addressing the potential adverse effects of the misleading information. Under no circumstances may the researcher provide the participant with misleading information on key aspects of the research that could influence his/her willingness to participate, such as risks, discomforts or adverse effects.

h. A statement confirming that the participant's anonymity will be guaranteed if he/she chooses to take part in the research and that no personal information will be provided to third parties without his/her permission (also see A7).

i. A clearly worded paragraph explaining that participation is voluntary at all times and that participants may refuse, without giving reasons, to take part in the research, discontinue their participation at any stage or decide that their information may not be used after the research has ended (within a period of 24 hours after the end of the experiment). In no event will such a decision have adverse consequences for the participant or his/her study results, etc. Any reimbursement 'earned' by the participant up until that moment will be paid out (in proportion to the duration of his/her participation).

j. If there is any likelihood of incidental findings, (see A5), the applicable procedure must also be explained. *The participant must expressly consent to this procedure by means of an extra signature on the informed consent form.*

k. The procedure for debriefing the participant after the experiment has concluded, if such a provision has been made, and the individuals involved in this debriefing and their positions.

The informed consent form signed by the researcher and participant must state that the participant has read and fully understands the contents of the information brochure (if the information brochure and informed consent form are separate documents, the form must feature a clear reference to the relevant information brochure). In the case of any additional stipulations (regarding screening, incidental findings, debriefing), the participant will sign separately for these procedures after having filled out all the required information (such as the name and address of his/her doctor). The form must also feature all contact addresses as listed in the information brochure (see above, points a and b). The participant will be given a copy of the form, and - if desired - a copy of the information brochure to take home.

Researchers may deviate from the above informed consent procedure in the following cases:

i. Research projects in which the participant fills out a questionnaire without any direct interaction with the research project leader. Examples include situations where the

questionnaire is sent to the participant by mail and filled out at home, or made available online. In such cases, the researcher will provide the above information by means of an enclosed letter or via the website, including the statement that participation in the questionnaire equates implicit permission (or a box that can be ticked by the participant). Here too, the participant is free to stop filling out the questionnaire at any time.

ii. If the participant cannot read or write, the researcher must obtain equivalent oral permission in the presence of a witness.[3] The EC will assess these cases separately.

A7. Anonymity

Information obtained from the research will not be made available to third parties (published, or presented at lectures or meetings with colleagues) in such a way that the results or other findings can be traced back to a specific participant. The only exception to this rule is the situation described under point A2.d, whereby the results from previous research are used as a selection criterion for new participants. In this case, information will be exchanged in encrypted form wherever possible (see example ii), and will not be made available to any individuals not involved in the research. Naturally, the information will be anonymised after the completion of data gathering, and will also be published and/or distributed in anonymous form.

In some cases, it may be valuable to use a specific participant's results for educational purposes (education, presentations at conferences, scientific documentaries, etc). If there is any danger that this could jeopardise the participant's anonymity (in the case of photographs, video or sound recordings, or 3D renderings of fMRI data, for example) the researcher must request the express consent of the participant before or after the experiment. Such information may only be used for the purposes for which the participant (or his/her authorised representative) has granted the researcher separate permission. This permission should ideally be granted in written form, but may also be granted orally if the participant cannot read or write. All information that could identify the participant will be stored and handled with care, and destroyed as soon as this is no longer detrimental to the research. In general terms, researchers are expected to act in accordance with privacy laws.

Also see the related subject 'copyright' (A10).

A8. Misleading and debriefing of participants

The misleading of participants is allowed under certain circumstances. In some cases, it is necessary to ensure that the participant does not have a clear idea of the experiment's exact purpose or procedure. Misleading is defined as providing the participant with inaccurate or incomplete information. The following chapter on the various standard research project types specifies the various permissible standard methods of misleading a participant for each research group.

The following general conditions apply when misleading a participant:

a. Participants may not be misled in terms of information on the potential risks of participation (also see A6.g).
b. Participants may only be misled if the questions cannot be answered properly without resorting to this method.
c. Participants must always be given a full debriefing to explain how they have been misled after the research is over. If there is any reason to expect that misleading of the

[3] WMO Sect. 6, paragraph 2.

participant could have temporary adverse effects, this debriefing must take place immediately after the experiment has concluded (for example, an immediate debriefing will be held if the subject has received false negative feedback on his/her language proficiency scores). This debriefing will be worded in such a way that any temporary adverse effects on – for example – the subject's self-image or mood are expected to be resolved immediately. If there is no reason to expect any temporary adverse effects, the debriefing may also be held at a later date, but no later than one month after the end of the experiment or sub-experiment; this means longitudinal research in which the participant is misled for a longer period of time must be submitted to the EC.

A9. Recruitment of participants

When recruiting participants, there is no need to provide all the information that will be included in the information brochure. However, potential participants must be informed of the following:

a) Whether or not the experiment will involve any discomforting procedures that are expected in advance to deter substantial numbers of potential participants from participating. This could include procedures that cause physical pain or have an extremely long duration, etc. Participants should not be informed about these procedures only *after* they have signed up for the experiment. This could create a situation in which a small number of participants are 'afraid' to say no. Furthermore, participants that withdraw from the research at this stage would still be entitled to a certain amount of reimbursement (see A6.i), thus requiring researchers to pay out many unnecessary reimbursements.
b) Whether or not certain groups of participants are excluded from the research or are advised against taking part due to a higher risk of adverse effects. This could include people with metal clips or implants in fMRI experiments, or pregnant women in experiments involving alcohol, etc. (also see A4).
c) Other examples include experiments involving materials that are offensive to or unsuitable for specific groups due to - for example - certain religious beliefs. This could include racist or sexually explicit photos or films, the consumption of alcohol, etc.

A10. Copyright

Participants hold the copyright on any audio or video recordings. The participant must fill out a form granting the researchers permission to use these recording for (1) research, and/or (2) public presentations at conferences, etc, and/or (3) publication on subscriber-only magazine websites and/or (4) non-copyright protected publication on the Internet or other mediums, depending on the researcher's intentions. This form is a good supplement to the points mentioned under point A7 (Anonymity).

B: Specific types of standard research

In order to be classified as 'standard research', a research project must fully comply with one of the descriptions below. The research project must also comply with all the preconditions for this specific type of research, and must be carried out by a researcher from one of the relevant disciplines (naturally, the research project must also comply with all the criteria listed under point A).

The disciplines mentioned below should not be interpreted as organisational units; in order for a research field to be classified as an individual discipline in the context of the EC, the relevant EC member must be familiar with the various sub-types of research conducted within that field. At the time of writing (June 2010), the EC distinguishes between the following disciplines: phonetics, psycholinguistics, second language acquisition, sign language, Dutch; the EC may supplement this list at a later date.

This document is based on the protocol applied by the Psychology Department, where different sub-types of research need to be classified as 'standard' for each research group. Specific sub-types regarded as standard by one research group or discipline (and thus listed under B) are not necessarily regarded as standard by other research groups or disciplines; if a member of the other group or discipline wishes to carry out such a research project, they will have to submit it to the EC in its entirety. This procedure has proven to be efficient at the Psychology Department: each research group can propose its own standard research projects without having to bother other groups. However, this approach may be less efficient in the case of linguistic research groups: (1) familiarity with the various sub-types of research may also vary *within* a specific discipline, and (2) there is only one experimentation facility (Bungehuis room 344-346), managed by a single technical support staff member (Dirk Jan Vet of the Phonetics Department). For this reason, we currently apply only one list of criteria for all linguistic research.

Linguistic research

This form of research is carried out by researchers from the following research groups: phonetics, psycholinguistics, second language acquisition, sign language, Dutch (this list may be supplemented at a later date).

B.0 Explanation of criteria A

Re. Al (Review by the EC or METC): Linguistic research is generally of a non-clinical nature. Researchers study fundamental linguistic functions, such as the comprehension and production of speech and language. In some cases, they also assess how these processes are implemented in the brain. The latter type of research involves the use of psychophysiological methods that are also applied in medical research, such as EEG or fMRI scans. When applied according to the protocol described here, the risk involved will be negligible. For the purpose of determining whether the research project is to be reviewed by the EC or METC, these methods are thus classified under category D (see Appendix 1, 2.4). However, minor variations must be carefully assessed, as they may affect the procedure for selecting the appropriate review body.

Re. A2 (Selecting adult, mentally competent participants): In addition to adult, mentally competent participants, selected according to the procedure described under point A2,

linguistic researchers also make use of minor (underage) participants. These participants are babies or children taking part in the research project on a voluntary basis with the permission of their parents or guardian. In view of the fact that this type of research will not be compliant with criterion A2 under any circumstances, it must always be submitted to the EC in its entirety; in most cases, the question of whether the research could not have been carried out with adult participants will be a key assessment criterion (see Appendix 1, paragraph 2.5).

Babies or children are generally recruited according to the procedure described in A2e or A2c, namely through schools, care centres or advertisements. In some cases, minor participants will be recruited using lists obtained from municipal authorities, who generally apply privacy restrictions. Special regulations apply with regard to informed consent (see A6).

The Faculty of Humanities has taken out a collective accident insurance policy to cover accidents involving children being tested at the phonetics laboratory. This policy covers the risk of accidents during their stay at the laboratory and transportation to and from the facility. The researcher responsible for overseeing the project must inform the appropriate secretariat (of the Phonetics Department, for example) about the children's participation in laboratory research, and must make sure to do so in a timely fashion. Participants will not be charged for the cost of additional insurance coverage. It is recommendable to ensure that other groups visiting the laboratory for research purposes, such as elderly participants, are also covered by this policy. Within the framework of the policy conditions, the UvA's liability insurance will cover (non-invasive) research procedures, insofar as the WMO does not specify any specific requirements for the insurance of participants. This coverage extends to both damage to equipment and bodily harm to/of the participant and researchers. The coverage applies to UvA researchers and visiting researchers. The insurance policy also extends to external (and commercial) research, as long as this research is being carried out by UvA employees. All claims are subject to a compulsory excess of €25,000. If the WMO specifies the need for further insurance, the researcher responsible for the research project must submit an application for participant insurance in a timely fashion. This application must be accompanied by a research proposal (WMO application). The contact person for any questions regarding UvA insurance policies is p.wurtz@uva.nl

Re. A4 (Screening of participants): Provisions regarding screening are especially important if the research will involve EEG or fMRI scans.

Re. A5 (Incidental findings): Provisions regarding incidental findings are especially important if the research will involve EEG, fMRI scans or hearing tests.

Re. A6 (Informed consent): In all cases, the participant will sign an informed consent form prior to participating in the research, unless the participant is under the age of 18. In this case, the following procedure will apply:

a) if the child will be supervised by a parent or guardian during the research – generally carried out at the laboratory – the parent or guardian must sign an informed consent form; b) if the research is being conducted at a host institute at which children are interned, and the management of this institute has legal authority to decide on participation in the research without consulting the parents or guardian (evidence of which must be provided to the EC), an informed consent form will be filled out by or on behalf of the institute's management; c) if the research project is being held at a host institute at which the child is not interned (such as a school), and researchers do not expect an active informed consent procedure to generate sufficient positive response, a passive informed consent procedure may be applied. The management of the host institute will then consent to and cooperate with the procedure by distributing (or commissioning the distribution of) comprehensive informed consent information to the parent(s) or guardian in a timely (no later than two weeks before the start of the research) and effective fashion, offering the parent(s) or guardian the opportunity to

inform the management (either orally or in writing) that they do not grant consent for the participation of their child. In order to ensure effective distribution of the necessary information, the parent(s) or guardian must be informed individually in a timely fashion by means of a letter drawn up by the researcher; this letter must be either handed to the parent or guardian in person or sent by email (in envelopes with a UvA stamp-postmark) by either the researcher (if he/she has been provided with the relevant addresses by the host institute) or the management of the host institute itself. The handing out of letters to children or provision of passive consent information by means of a newsletter or other comparable medium offers insufficient certainty that information will be distributed in a timely and effective fashion, and is thus not permitted.

At minimum, the informed consent form or information issued to the parent(s) or guardian in the case of a passive informed consent procedure must include all the information outlined in point A6. For an example, see Appendix 4.

Re. A8 (Misleading the participant): In the case of auditory experiments, the participants may be misled in terms of the source language of the stimuli.

B1. Psychoacoustic or behavioural tasks

This concerns experiments in which the participant carries out a task while being presented with auditory or visual stimuli, or combinations thereof. This could include experiments in the area of speech perception, language comprehension, linguistic memory, etc. The participant will sit or lie down in a test environment consisting of stimulus equipment (such as a computer monitor, loudspeaker) and equipment or other means of registering his/her behaviour (buttons, pedals, microphone, pen and paper, etc). The participant will not spend more than four hours in the test environment (less than two hours in the case of participants under the age of 18, less than one hour in the case of participants under the age of 6, and less than half an hour in the case of participants under the age of 2), and will not take part in such experiments more than three times a week. The participant's head may not be secured. The participant will respond to prompts by means of his/her voice or hands and feet. In some cases, the participant will be monitored using a CCTV system; audio or video recordings of the participant may be made as a part of the experiment, providing the necessary provisions in terms of anonymity (A7) and copyright (A10) are adhered to.

The stimulus material must be emotionally neutral, consisting of abstract shapes, simple images, domestic scenes, meaningless audio tones, neutral words, etc. In the case of visual stimulation, the degree of light emitted by the stimulus equipment must be harmless. The volume of any audio stimuli must also be harmless to the participant's hearing.

In all other cases (such as experiments involving emotionally charged stimuli), the full range of stimuli (and the experiment as a whole) must be submitted to the EC in its entirety. This also applies in the case of somatosensory or olfactory stimulation, or experiments based around the use of performance-based rewards (or punishment). If the experiment will involve the use of emotional stimuli, this must be clearly explained in the informed consent form.

B2. Speech or language production tasks

This concerns experiments in which the participant carries out a task involving the production of speech, language or song. In some cases, the participant will be required to read from a screen or sheet of paper. In other cases, the participant may be required to read out a monologue or interview on an emotionally neutral subject.

The participant will have to sign a consent form authorising the use of any audio or video recordings.

Some experiments – such as those requiring the subject's oral response to auditory stimuli or dialogues - may involve a combination between B1 and B2.

B3. EEG or ERP measurements

This concerns the type of experiments defined under B1, whereby the participant is wearing a maximum of 64 EEG electrodes (a maximum of 32 in the case of children of 12 and under, and 12 in the case of children of 4 and under), attached by means of an electrode cap, or a maximum of 24 electrodes (a maximum of 16 in the case of children of 12 and under, and 12 in the case of children of 4 and under) attached individually by means of collodion. Measurements are conducted using one of the following EEG systems: Biosemi, BrainProdukts, MedCare, Neurotop, Nikon-koden, Neuroscan or EGI. All measurements are carried out in accordance with the 'hygienic working methods' guidelines (see Appendix 3). The participant will not be required to sit for measurements for longer than two hours, and will not take part in experiments more than twice a week. The participant's head will not be secured during measurements.

B4. Functional MRI

This concerns experiments such as those defined in B1, whereby the participant is placed in an MRI scanner. The experiments will be conducted using either one of the VU University Amsterdam's 1.5T Siemens Sonata scanners or the UvA-AMC's 3T Philips scanner. According to normal procedure, the participant will be lying on a moveable table that can be moved in or out of the scanner 'tunnel'. As a result, this type of experiment may not be suitable for people with claustrophobic tendencies. Participants must be screened for this condition in advance.

At the time of writing (June 2010) the national Central Committee on Research Involving Human Subjects (CCMO; http://www.ccmo.nl) prohibits all fMRI research involving children under the age of 8 ('MRI without anaesthetic, participants under the age of 8: not acceptable'), and has the power to overturn METC rulings. The CCMO bases its decision on Section 4, paragraph 1 of the Medical Research (Human Subjects) Act: 'No medical research may be carried out on participants that are under the age of eighteen or are incapable of accurately weighing their own interests in this matter. This exclusion does not apply to medical research that may also benefit the participants themselves and scientific research that cannot be carried out without the participation of participants from this category involving a negligible risk and minimal adverse effects'. Under strict preconditions (such as the presence of a replica scanner to allow the participant to practice and become accustomed to the procedure) the CCMO has approved fMRI research on children of age 8 and upwards. This research was subject to monthly monitoring by an METC. In the absence of any decisions to the contrary or relevant precedents, all fMRI research involving children must be submitted to the CCMO, and fMRI research on children under the age of 8 is prohibited.

The participant will not spend more than 60 consecutive minutes inside the scanner, and may not be required to keep still for longer than 20 minutes at a time. The participant will not take place in the scanner more than 3 times a day (not more than 2 times a day in the case of children age 12 and under), and will not take part in fMRI experiments more than 2 times a week. The participant's head will be lightly secured by means of headrests and a pillow. This will not cause any pain and the headrests will not be fastened tightly. However, the headrest will ensure that the participant remains still when in a relaxed state. MRI and fMRI scans will be made of the participants without the use of any contrast agents or anaesthetic. These scans will be conducted using a high-resolution head array coil from MRI Devices.

Visual stimulation will be provided by means of projections on a mirror above the participant's head, with auditory stimulation provided by means of headphones, according to the protocol described under B1. In view of the potentially hazardous effects of the noise emitted by the scanner, all participants will be provided with earplugs, or – in the case of auditory stimulation – protective headphones that reduce the sound to a non-hazardous level.

Measurements may also involve the use of eye-tracking equipment (Eyetracker from Resonance Technology Inc. will be used in combination with the UvA-AMC 3T scanner). This eye tracker is basically a camera positioned approximately 5 cm from the participant's eye (the camera does not contain any metal components).

Prior to the research, all participants will be extensively screened for any conditions that could raise the risk of an fMRI experiment to 'non-negligible' level. At minimum, this will serve to exclude the presence of any metal components in or around the head, such as cochlear implants, arterial clips, surgical prostheses, plates, screws, etc.

B5. Other psychophysiological measurements

This includes all measurements described under B3 ('EEG or ERP measurements') whereby the EEG measurements have *been replaced or supplemented* by/with **one** of the following measurements:

a. The registration of eye movements or pupil dilation using a video-based eye tracker system. Such measurements will be carried out using the Tobii system from the Phonetics Lab.
b. GSR, EOG or EMG measurements by means of electrodes attached to the skin will be conducted using Biosemi, BrainProdukts, Neurotop, Nikon-koden or Neuroscan systems, or equipment developed in-house consisting entirely of components that have been issued individual ICE quality marks or designated as safe by the technical support service. All measurements are carried out in accordance with the 'hygienic working methods' guidelines (see Appendix 3). Skin irritation, especially in the facial region, must be prevented by taking adequate measures, such as the timely application of ointments. In the case of a facial EMG, no more than two bipolar leads will be measured at once.

B6. Questionnaire-based research

All research involving questionnaires or interviews (for the purpose of developing the measuring instrument or answering substantive questions) can be regarded as standard research. However, if such instruments are applied to patient groups or if their use may trigger highly emotional responses (such as research involving questions on traumatic experiences), the research project must be submitted to the EC in its entirety (or to the METC) for assessment. Characteristics of questionnaire-based research:

a. Respondents individually (in a classroom setting, in some cases) fill out questions about themselves, their environment or other people in their environment (children, age group peers, pupils, friends, partners, fellow-students, etc), by means of a paper or digital questionnaire. Filling out this questionnaire will generally not take more than 1 hour.
b. Examples of questionnaire subjects: cognitive/intellectual skills (such as reading skills, learning skills, memory skills, IQ); learning styles; health-related variables and subjective health, etc.
c. Participants may only be misled if they (or, in the case of children, their parents/guardian) are informed about the purpose of the research and the manner in which they were misled during the research immediately after the research has concluded. This debriefing must be conducted in such a way that it can be reasonably expected to resolve any temporary adverse effects on the participant as a result of having been misled. In many cases,

participants will not be informed about the actual purpose of the research in advance, in order to prevent them from giving socially desirable answers.

d. If the research involves questions on emotionally-charged or sensitive subjects (such as conflicts, sexual behaviour, traumatic experiences, etc), the researcher must ensure that questions are worded in such a way that they do not have any adverse effects on the participant or his/her environment. All questions must be worded in a neutral manner, i.e., non-judgemental.
e. The research will not cause any physical discomfort, or health and safety risks.

4. Checklist for the submission of research projects to the EC

General

1. Project title
2. Responsible researcher (in the case of a doctoral research project, also state name of supervisor/doctoral thesis supervisor)
3. Researchers performing the research (doctoral candidates, students, etc, if known)
4. Discipline
5. Location where research is performed
6. Brief description of the project (approx. 200 words)
7. Expected duration of the project
8. Number of participants

Questions part A

1. Have you previously submitted similar research projects to the EC?
   □Yes,
   □ No

   If so, what number was allocated to the project by the EC?

   Explanation:

2. Does the research project fully comply with the provisions outlined in A1 in terms of its Medical/Non-Medical nature, justifying classification in category D (also see Appendix 1, paragraph 2.4)?
   □ Yes, the project can be classified under category D.
   □ No, the project can be classified under category A.
   □ No, the project can be classified under category B.
   □ No, the project can be classified under category C.
   □ Not sure; explain why you are not certain

   Explanation:

3. Will the researchers be selecting adult, mentally competent participants according to one of the procedures described under A2?
   □ Yes; indicate which of the procedures described under A2 will be applied
   □ No; please explain
   □ Not sure; explain why you are not certain

   Explanation:

4. Will the participants be taking part on an entirely voluntary basis and will they be free to discontinue their participation at any time, for any reason, as outlined under A3?
   □ Yes
   □ No; explain why not
   □ Not sure; explain why you are not certain

   Explanation:

5. If there is any potential need to screen participants (according to the procedure outlined in A4) in order to reduce the risk of adverse effects: Will the participants be screened?
   □ No need for screening; explain why not
   □ Yes; explain how the participants will be screened
   □ No; explain why not
   □ Not sure; explain why you are not certain

   Explanation:

6. Will any methods be used that could yield findings of which the participant should be informed (see A5)?
   □ No, the methods applied in this research project will not yield any such findings
   □ Yes, and the participant will sign a form consenting to the applied method (see A5)
   □ Yes, but the participant will not be signing a form consenting to the applied method (see A5)
   □ Not sure; explain why you are not certain

   Explanation:

7. Will the participants be provided with further information before the start of the research, and will they be signing an informed consent form in accordance with the procedures described under A6?
   □ Yes; enclose the information brochure and informed consent form
   □ No; explain why not
   □ Not sure; explain the nature of your doubts

   Explanation:

8. Will the research project be conducted in accordance with the anonymity and privacy guidelines described under A7?
   □ Yes
   □ No; explain why not
   □ Not sure; explain the nature of your doubts

   Explanation:

9. If the participants will be misled, is the procedure in compliance with the guidelines outlined under A8 (no misinformation regarding risks, accurate debriefing)?
   □ The participants will not be misled
   □ The participants will be misled in a manner entirely compliant with the guidelines outlined under A8 (provide further explanation)
   □ The participants will be misled in a manner that is not compliant with the guidelines outlined under A8 (provide further explanation)

   If the participants will be misled, enclose a document describing the debriefing method

   Explanation:

10. Is there reason to expect that a substantial number of participants will discontinue the research after having been recruited due to any discomfort caused by the research? (see A9).
    □ No
    □ Yes, possibly

    If so, enclose the recruitment advertisement, taking into account the guidelines outlined under A9

    Explanation:

Questions part B

11. Answer the following questions based on the relevant type of research

    The research project can be classified under the following discipline:
    - □ phonetics
    - □ psycholinguistics
    - □ second language acquisition
    - □ sign language
    - □ Dutch
    - □ other language, namely:

    Explanation

12. Does the research project fully comply with one of the standard research project descriptions featured in section B of the relevant research type?
    - □ Yes; go to question 13
    - □ No; go to question 14
    - □ Not sure; explain the nature of your doubts, and go to question 14

    Explanation

13. If so, provide further details on all aspects of the research project that are not mentioned in the description (for example: what sort of stimuli will you be using?, what sort of tasks will the participant be required to carry out?)

14. If the answer is no, or you are not sure, describe the research project in the greatest possible detail. If appropriate, refer to the standard descriptions and indicate how they differ from your research project. You must always provide all information that could be relevant to an ethical review.

Appendix 1. Review by the METC or EC?

1. Introduction

In which cases must a Faculty of Humanities research project be reviewed by a nationally accredited Medical Ethics Review Board (METC), and when will review by the Faculty of Humanities' local Ethics Committee (EC) suffice? It is not always clear how the Medical Research (Human Subjects) Act (*Wet medisch-wetenschappelijk onderzoek met mensen*, or WMO) should be interpreted in this regard. The Faculty of Humanities' EC adheres to the interpretation applied by psychologists from the ECs of Maastricht University, Leiden University and the University of Amsterdam (UvA), which has been elaborated in further detail below.

2.1 Selection criteria

Research involving people will require a medical ethics review if it is subject to the Medical Research (Human Subjects) Act (WMO).
Research is subject to the WMO if it meets the following two preconditions:

1. the research is of a medical nature, and
2. human participants will undergo some form of treatment or be required to comply with a certain form of behaviour.

2.2 Nature of the research project: medical or non-medical?

How do we define scientific medical research? Scientific research is defined as research whereby the systematic gathering and assessment of data yields answers to the predefined research questions, generally valid statements and new conclusions.
Research is thus based on a research question. Such research generally involves the publication of results. Pharmaceutical research is generally classified as medical research. In some cases, behavioural research is also regarded as medical research.[4]

2.3 Degree of risk: negligible or non-negligible?

The WMO does not feature any further definition of risk (or adverse effect). In operational terms, we regard research as hazardous if – as a direct result of the research being conducted, regardless of whether this is due to misleading of the participant or stimuli with the potential to induce emotions or stress (in the broadest sense of the word) – the participant or any third parties involved run a more than negligible risk of:

1. disclosure of private information;
2. addiction (physical or psychological) to an act carried out as part of the research (such as gambling) or a product administered during the research;
3. any mental disorder, mental distress or psychological trauma that is of a permanent nature or is serious enough to require therapeutic or psychiatric treatment or prescription medication;
4. physical injury, allergic reactions, discomfort or pain that is either of a permanent nature or serious enough to require medical treatment or prescription medication.

[4] Source: http://www.ccmo-online.nl. main.asp?pid=10&sid=30&ssid=51.

2.4 Nature of the research & degree of risk: assessment table

Based on the criteria described in further detail in 2.1, 2.2 and 2.3, we have drawn up the following table:

Selection criteria 2.1		Degree of risk	
		Non-negligible	Negligible
Nature of the Research:	Medical	A (METC)	B (METC)
	Non-medical	C (EC, may require consultation of METC)	D(EC)

2.5 Mental incompetence

According to Section 4 of the WMO, researchers are prohibited from conducting scientific research on participants under the age of 18 (and individuals regarded as mentally incompetent on the basis of factors other than age). As regards this category of participants (mentally incompetent individuals), the WMO applies a 'no, unless' principle. Section 4 features the following exceptions

1. 'research that may also benefit the participants themselves'; and
2. 'research that cannot be carried out without the collaboration of participants from the category to which the participant belongs and which involves a negligible risk and minimal adverse effects'.

This type of research is always categorised in category A, unless it involves individuals regarded as mentally incompetent on the basis of their age (children), in which case the research will be classified under category B or D.

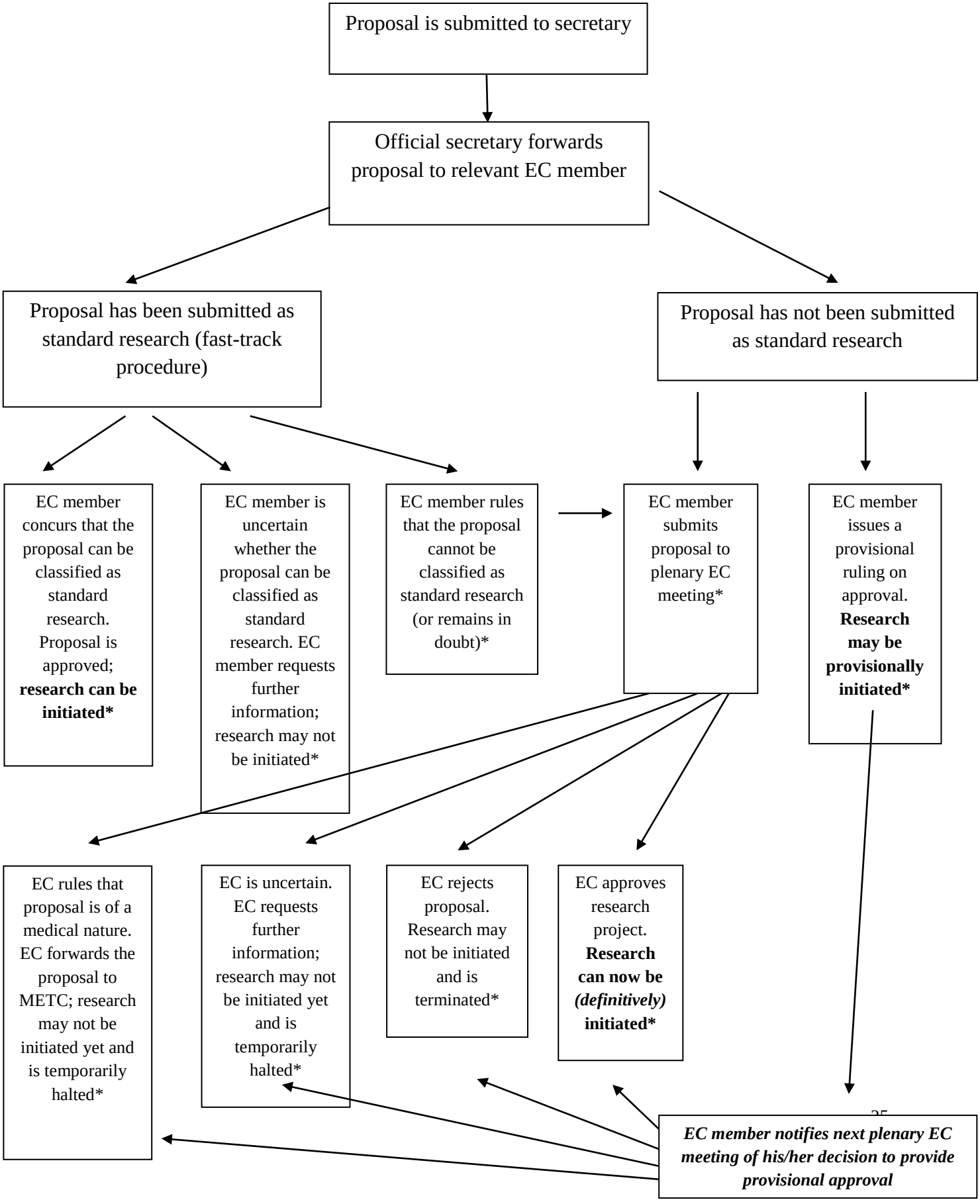
2.6 Summary of review guidelines

All medical research must be reviewed by an METC. Non-medical research is initially reviewed by the Faculty of Humanities' EC. The degree of risk or discomfort to which the participant will be exposed is also relevant in this regard. If necessary, the EC will seek expert advice in order to reach a more well-founded decision on the degree of risk to which participants may be exposed. If this risk is of a medical nature (affecting the participant's health), the EC will seek the advice of an accredited METC. In other cases, the EC may seek the advice of experts in another field (such as a lawyer, ethicist).

The use of medical or paramedical equipment (such as MRI scanners, EEG, blood pressure meters or other physiological measuring instruments), and other physical procedures (such as exposure to extreme conditions), or procedures that evoke or require physical reactions (such as effort) can all pose a potential risk, or may do so for specific groups. With the exception of the procedures described in section B, the use of such equipment or procedures must always be submitted to the EC before any definitive conclusions can be drawn in terms of the risk they pose to participants.

Research involving mentally incompetent participants must always be assessed against the exceptions clause mentioned in Section 4 of the WMO (see 2.5, above)

2.7 Flow chart for review of research projects by EC
(* means that the secretary informs the researcher about the status of the submission and/or the EC's decision)



Appendix 2. Composition of the EC

Faculty of Humanities Ethics Committee
c/o Research Department
Spuistraat 210
1012 VT Amsterdam
Tel: 020 - 525 3266
Fax: 020 - 525 4708
Email: commissie-ethiek-fgw@uva.nl
Internet: www.hum.uva.nl/onderzoek

Chairman
Professor Paul Boersma *(Phonetics)*

Secretary:
Drs René Does
Room: Bungehuis 117

Psycholinguistics and Sign Language
Professor Anne Baker

Second language acquisition
Dr Rob Schoonen

Dutch
Professor Fred Weerman

Ethics
Professor Beate Roessler

Appendix 3. Guidelines for hygienic working methods

GUIDELINE FOR HYGIENIC WORKING METHODS

This section must be filled in when any relevant equipment (such as an EEG scanner) is being used at the Faculty of Humanities. The EC document applied by the Psychology Department may be used as a template.

APPENDIX 3D. OVERVIEW OF RELEVANT PHONE NUMBERS AND EMAIL ADDRESSES

Emergency number for life-threatening situations	0112
Emergency number for other calamities	(020-525) 2222
	6260
	5222

Technical Support for Phonetics Research:

Dirk Jan Vet	d.j.vet@uva.nl	(020-525)2188

Appendix 4. Standard examples of information brochures and informed consent forms

Information brochure and informed consent form for researchers

According to the APA manual, all participants must be provided with an information brochure and sign an informed consent form. This procedure is intended to ensure that:

(1) all participants are made aware of the purpose of the research in which they will be taking part, as well as the discomforts, risks, etc, involved. Potential participants should have enough information to make a balanced decision on whether or not to participate in the research .
(2) participants are aware that they may discontinue their participation at any moment, and know what will happen to their data, etc.

You must always ensure that the information provided to participants is accurate, and tailored to the exact specifications of your own research project. The examples below are merely illustrative. In some cases, these examples can be tailored to your own research.

Information brochure
The section below features examples of information brochures that can be adjusted to reflect the specifications of your own research proposal. The majority of research projects consist of standard research. We have also included examples of information brochures for research with the potential to yield incidental findings, research which requires the consent of the parent in the case of research on children and research involving passive informed consent.

Informed consent
Various examples of informed consent forms that can be tailored to the specifications of your own research are given below. These examples comprise:

a) standard research;
b) standard research and ‘incidental findings from fMRI scans’;
c) standard research plus parental consent in the case of research on children;
d) standard research involving passive informed consent.

Informed consent forms (‘toestemmingsverklaring.pdf’) can be downloaded from the website.

Information brochure for standard Linguistics research

'Distributional learning of auditory categories: adults'

Dear participant,

You will be taking part in the **'Distributional learning of auditory categories'** research project conducted by the University of Amsterdam (Language and Literature Department). Before the research project can begin, it is important that you read about the procedures we will be applying. Make sure to read this brochure [or: the following information] carefully.

Purpose of the research project
[Example of an abridged version:] Over the course of this experiment, you will be listening to the sounds of human speech. The experiment aims to find out how effectively people can learn a language by simply listening to it.
[Example of a longer version (for example, the text of a brochure for participants to read at home):] As we know from prior research, babies learn a great deal about their mother tongue during their first year. They do this by listening to the language being spoken around them, before they are actually able to understand what is being said. — Over the course of this research, we will be attempting to find out how effectively adults can learn a language by simply listening to it. We will then compare our findings with the learning behaviour displayed by babies under the same circumstances. This will help us find out how people learn a language by simply listening to it. It will also help us determine how our ability to learn a language changes over the course of our lives. — This research is important because it offers insight into one of the most important skills babies and young child learn: understanding and speaking their mother tongue. It will also help us understand why adults often find it more difficult to learn a new language.
[If the participants will be misled to any extent, you might add something like:] At this stage of the project, we cannot provide any further information on the factors we will be examining. You will receive further details after the experiment has ended.

Who can take part in this research?
[As a rule of thumb, this section will only be relevant if participants are to be screened, which generally is the case during linguistic research projects (selection on the basis of language background, age, hearing problems...)]
We are inviting adult speakers of the Dutch language to take part in this research. Before the experiment begins, we will be asking you some questions about your hearing and eyesight. In view of the nature of the research, it is important that you have good hearing and eyesight. You may wear glasses or contact lenses. — We will also be asking a number of questions about your language background. You can take part in this research project if Dutch is your mother tongue and you were not brought up in a bilingual household. We also need to make sure that you do not – to the best of your knowledge — have any language problems such as dyslexia or a specific language disorder.

Instructions and procedure
During the first part of the experiment, you will be alone in a research laboratory. The researcher will be in the room next door. She will be able to see you through a window and hear you via a microphone. You will then hear a number of sounds over the loudspeakers, at a

volume of approximately 70 dB. You will then be requested to answer questions about these sounds on a computer. This task will take approximately ten minutes.

During the second part of the experiment, we will ask you to copy a photo as accurately as possible by drawing a picture of the image. In the meantime, you will hear a series of sounds. This time, you will not have to pay attention to what you hear. This part of the experiment will last 15 minutes.

In the third part of the experiment, you will be seated in front of a Tobii eye-tracking screen. A bar in the bottom section of the screen contains an infrared lamp that will shine on your face. This allows the infrared camera in the screen to track your eye movements and the size of your pupils. The infrared light in harmless and invisible to the naked eye. The data from the eye tracker will be stored and analysed at a later stage of the research project. A separate video camera will also record your face and the sounds in the room. The researchers will only use this material if the eye-tracking signal is not clear enough.

First, the system will calibrate the machine to your eyes. You will see a moving ball on screen, which you must follow with your eyes. This will take several minutes.

You will then hear sounds similar to those played during the first part of the experiment. In the meantime, you will see circles on screen. Every ten seconds, a moving ball will appear. You may blink as you normally would, and move your eyes around the screen. This will take five minutes.

The final part of the experiment is identical to the first, and will last 10 minutes.

Voluntary participation

You will be participating in this experiment on a voluntary basis. This means you are free to stop taking part at any stage. This will not have any personal consequences and you will not be obliged to finish the procedures described above. You can also decide to withdraw your participation up to 24 hours after the experiment has ended. If you decide to stop or withdraw your participation, all the information gathered until that point will be permanently deleted.

Insurance

In view of the fact that this experiment does not involve any health or safety risks, we have not taken out any special insurance policies.

Confidential treatment of your details

The information gathered over the course of this experiment will be used for publication in scientific journals. Your personal details will not be used in these publications, and we guarantee that you will remain anonymous under all circumstances.

The data gathered during the experiment will be encrypted and stored separately from your personal details. These personal details and the encryption key are only accessible to members of the research staff.

The eye-tracking, video and audio recordings will never be shown in public without your written consent. After the research project has been completed, you will receive a separate form to provide such consent if you wish to do so.

Reimbursement

You will receive a 10 euro reimbursement for taking part in the research project. If you wish, we can send you a summary of the general research results at a later stage.

Further information
For further information on the research project, please contact researcher… (phone number: 020-525...; email: ...@uva.nl; Spuistraat 210, 1012VT Amsterdam, room ...). If you have any complaints regarding this research project, you can contact the secretary of the Ethics Committee of the University of Amsterdam's Faculty of Humanities, commissie-ethiek-fgw@uva.nl (phone number: 020-525 ….; Spuistraat 210, 1012 VT Amsterdam).

Information brochure on standard research project plus parental consent in the case of Linguistic research on children.

'Distributional learning of auditory categories: babies'
Information brochure for parents

Dear parent/guardian,

You and your baby will be participating in the **'Distributional learning of auditory categories'** research project conducted by the University of Amsterdam (Language and Literature Department). Before the research project can begin, it is important that you read about the procedures we will be applying. Make sure to read this brochure [or: the following information] carefully.

Purpose of the research project
[Example of an abridged version:] Over the course of this research project, your baby will be listening to the sounds of human speech. The experiment aims to find out how effectively people can learn a language by simply listening to it.
[Example of a longer version (for example, the text of a brochure for participants to read at home):] As we know from prior research, babies learn a great deal about their mother tongue during their first year. They do this by listening to the language being spoken around them, before they are actually able to understand what is being said. — Researchers at the University of Amsterdam are conducting a research project to find out how babies become familiar with a language's sound structure by simply listening to the sounds around them. — We will start by playing your baby the sounds of an unfamiliar language. We will then carry out tests to determine which differences between these sounds your baby can identify. Obviously, babies cannot tell us what we would like to know through speech, so we will determine what they know from the way in which they look at pictures while listening to sounds. — This research is important because it helps us to understand how babies discover patterns in the stream of sounds they hear around them. This will help us gain more insight into one of the most remarkable skills babies and young children learn: understanding and speaking their mother tongue.

Who can take part in this research project
[As a rule of thumb, this section will only be relevant if participants are to be screened, which generally is the case during linguistic research projects (selection on the basis of language background, age, hearing problems...)]
We have invited 6-month old babies to take part in this research. — Before the start of the experiment, we will be asking you a number of questions about your pregnancy, the birth of your baby, and its development until now. Your baby can take part in the experiment if he or she was born on time and without complications, and is developing normally. In view of the nature of the research, it is also important to make sure there are no problems with your baby's hearing or eyesight. — We will also be asking you a number of questions about the language you speak at home and both parents' language background. Your baby can take part in the experiment if its mother tongue is Dutch and it is generally surrounded by Dutch speakers. We also need to make sure that neither of the baby's (biological) parents has any language problems such as dyslexia or a specific language disorder.

Instructions and procedure

During the first part of the experiment, you and your baby will be in the research laboratory together. The researcher will be in the room next door. She will be able to see you and your baby through a window and hear you via a microphone. We will then play various sounds over the loudspeakers, at a volume of approximately 70 dB. You do not have to pay attention to these sounds. However, we will ask you to speak to your baby as little as possible while the sounds are being played. This part of the experiment will last about 8 minutes.

For the second part of the experiment, you will place your baby in a car seat in front of a Tobii eye tracking screen. A bar in the bottom section of the screen contains an infrared lamp that will shine on your baby's face. This allows the infrared camera in the screen to track your baby's eye movements and the size of its pupils. The infrared light in harmless and invisible to the naked eye. The data from the eye tracker will be stored and analysed at a later stage of the research project. A separate video camera will also record your baby's face and the sounds in the room. The researchers will only use this material if the eye-tracking signal is not clear enough.

The researcher will be with you in the research laboratory for a few moments at the start of the experiment. She will make a moving ball appear in various parts of the eye-tracking screen. As your baby follows the ball, the system will automatically calibrate the eye tracker to its eyes. The will take about 5 minutes.

The researcher will then leave the research laboratory, and the test will begin. Your baby will hear sounds similar to those played during the first part of the experiment. In the meantime, circles will appear on the screen. A moving ball will appear every ten seconds, to draw your baby's attention to the screen. You will be sitting on a chair behind your baby, listening to music on a pair of headphones. We will ask you to make as little contact with your baby as possible during the experiment, so that we can observe its spontaneous reactions. The will take about 5 minutes.

Voluntary participation

You and your baby will be participating in this research project on a voluntary basis. This means you are free to stop taking part at any stage. This will not have any personal consequences and you will not be obliged under any circumstances to finish the procedures described above. You can also decide that you would rather not participate up to 24 hours after the experiment has ended. If you decide to stop or withdraw your participation, all the information gathered until that point will be permanently deleted.

Insurance

The risks of taking part in this research are no greater than in normal everyday situations at home. In view of the fact that your baby is a minor, the university has taken out a term life insurance policy for your baby for the duration of the research project and travel to and from the university.

Confidential treatment of your details

The information gathered over the course of this experiment will be used for publication in scientific journals. No personal details will be used in these publications, and we guarantee that your baby will remain anonymous under all circumstances.

The data gathered during the experiment will be encrypted and stored separately from your baby's personal details. These personal details and the encryption key are only accessible to members of the research staff.

The eye-tracking, video and audio recordings will never be shown in public without your written consent. Once the experiment has finished, you will receive a separate form to provide such consent if you wish to do so.

Reimbursement

As a token of our appreciation for your participation, you and your baby will receive a small gift, and a certificate featuring your baby's name and the title of the research project. If you wish, we can send you a summary of the general research results at a later stage.

Further information

For further information on the research project, please contact researcher Dr xxx (phone number: 020-525...; email: xxxx@uva.nl; Spuistraat 210, 1012VT Amsterdam, room ...).
If you have any complaints regarding this research project, you can contact the secretary of the Ethics Committee of the University of Amsterdam's Faculty of Humanities, commissie-ethiek-fgw@uva.nl (phone number: 020-525…; Spuistraat 210,1012 VT Amsterdam).

Information brochure for standard Linguistic research involving children - PASSIVE INFORMED CONSENT.

'XXXX' [title of research project]

Dear parents/guardians,

Your child's school is participating in the XXXX research project conducted by the University of Amsterdam's XXX research institute. The section below provides further information on the exact nature of the experiment. This type of research cannot be carried out without the participation of children in the XX-XX age group. Most children enjoy taking part in this type of research. The school board regards participation in this research project as useful, and does not feel your child's participation would go against its interests or those of the school. The research will take place at school, and will be scheduled around your child's lessons.

Before the research can begin, it is important that you read about the procedures we will be applying. Please make sure to read the information below carefully.

Your child will be participating in the research in the week of XXXXX. If you object to your child's participation in the research, you can inform the school board or the researchers (see 'Passive Informed Consent', at the bottom of this letter).

Purpose of the research project.

This research was set up in order to study xxx. The purpose of the research is xxx. You will be informed about the exact nature of the research after the experiment has finished.

Instructions and procedure

Over the course of the experiment, your child will be required to xxx. Your child does not need to have any experience with computers to carry out this task. The computer screen will display xxxx. Your child will then xxx. The test will last approximately xxxx, including breaks. The test is not especially difficult or strenuous. Before the start of the test, your child will be given a detailed explanation and the opportunity to practice, so that it clearly understands the test and can carry out the required tasks without any problems. Due to the nature of the research, the test will be very similar to a game, and is suitable for children.

Voluntary participation

You are free to decide that you do not want your child to take part in the experiment. Your child is also free to decide that it does not want to take part or decide it wants to stop taking part at any stage of the project. You or your child do not have to give any reason for your decision, and this decision will not have any negative consequences for your child. You can also decide to withdraw consent for the use of your child's information within 24 hours after the end of the experiment. If your child decides to stop taking part, or if you withdraw your consent within 24 hours, your child's information will be removed from our files and destroyed.

Discomfort, risks and insurance

As we know from previous, similar research, participants experience little or no discomfort. In view of the fact that this experiment does not involve any health or safety risks for your child, we have not taken out any special insurance policies.

Confidential treatment of research data
The data gathered over the course of this research will only be used for further analysis and – in some cases – publication in scientific journals. No personal details will be used in these publications, and we guarantee that your child will remain anonymous under all circumstances.

Further information
If you have any questions before or after the start of the experiment, please contact the responsible researcher, Dr X, tel. 020 525…, email xxx@uva.nl; address ….
If you have any complaints regarding this research, you can contact the secretary of the Ethics Committee of the University of Amsterdam's Faculty of Humanities, commissie-ethiek-fgw@uva.nl (phone number: 020-525…; Spuistraat 210, 1012 VT Amsterdam).

Information brochure for standard research and 'incidental findings from fMRI scans'

[this will have to be filled out if the Faculty of Humanities starts conducting fMRI-research; the procedure applied by the Psychology Department can serve as an initial example]

Procedure for incidental findings

For your information: the Psychology Department applies the following procedure for incidental findings during fMRI research.

The participant signs the informed consent form, granting permission to inform his/her doctor in the event of an incidental finding. The research leader is prohibited from informing the participant about the incidental finding. For this reason, participants should never be allowed to see their own MRI scans after the measurement has taken place, even if there has been an incidental finding.

If possible, the research leader will also make a T2/PD scan without the participant noticing (the participant will be told something along the lines of: we need to do another scan to measure the sensitivity of the head coil). The research leader will leave both the 3DT1 scan and the T2/PD scan in the hospital database. The research leader will report the incidental finding to the fMRI coordinator and provide him/her with the contact information for the participant's doctor. The fMRI coordinator will then contact one of the neuroradiologists, who will check the MRI scan and contact the participant's doctor if necessary.

Screening of participants prior to MRI scan

Have you been fitted with a pacemaker or do you still have any (old) pacemaker leads inside your body?	yes / no
Have you ever undergone a neurosurgical procedure?	yes / no
Do you have any clips in your head as the result of an operation?	yes / no
Do you have a medicine pump (such as an insulin pump)?	yes / no
Do you have an artificial heart valve?	yes / no
Do you have a neurostimulator?	yes / no
Do you have an artificial lens attached with metal clips?	yes / no
Do you have a non-removable hearing aid?	yes / no
Do you have one or more metal ear tubes?	yes / no
Do you have an external prosthesis (such as a prosthetic arm?)	yes / no
Do you have a dental bridge?	yes / no
Are you pregnant?	yes / no
Have you ever sustained a head injury?	yes / no
Have you ever suffered from an illness that resulted in brain damage?	yes / no
Are you epileptic, or do you have any epileptic family members?	yes / no
Have you ever had a stroke?	yes / no
Do you suffer from: Claustrophobia?	yes / no
Do you suffer from: Shortness of breath (when lying down)?	yes / no
Do you have one or more piercings?	yes / no
Do you have one or more tattoos?	yes / no
Do you have orthodontic braces or permanent retainers?	yes / no
Are you currently using psychopharmaceuticals?	yes / no
Are you colour blind?	yes / no
Do you wear prescription glasses?	yes / no
Do you wear contact lenses?	yes / no

If you wear glasses or contact lenses, what prescription do you have?
Left = Right =

The potential participant will also be checked for visual acuity (Snellen chart), colour blindness (Ishihara test), and depth perception (Stereograms).

a) Informed consent form for standard research

'I hereby declare that I have been clearly informed about the nature of the research and the methods used, as described in the [or: above] "XXXX" information brochure. My questions have been answered to my satisfaction.

I have consented to participate in this research on an entirely voluntary basis. I retain the right to revoke this consent without having to provide any reasons for my decision, and am aware that I am entitled to discontinue the experiment at any time. If my research results are used in scientific publications or made public in any other way, they will be fully anonymised. My personal information may not be viewed by third parties without my express permission.

If I need any further information on the research, now or in the future, I can contact XXXX (phone number: XXXX email: XXXX; Spuistraat 210, 1012 VT Amsterdam, room xxx).

If I have any complaints regarding this research, I can contact the secretary of the Ethics Committee of the University of Amsterdam's Faculty of Humanities, commissie-ethiek-fgw@uva.nl (phone number: 020-525 xxxx; Spuistraat 210, 1012 VT Amsterdam).

Signed in duplicate:

…… ……
Name of participant Signature

[A section on broader use of the audio and video recordings can also be included here. The participant must sign separately for this consent, and must be made aware that he/she is transferring his/her copyright.]

'I have explained the research in further detail. I hereby declare my willingness to answer any further questions on the research to the best of my ability.'

…… ……
Name of researcher Signature

……
Date

b) Informed consent form for incidental findings during research involving fMRI

'I hereby declare that I have been clearly informed about the nature of the research and the methods used, as described in the [or: above] "XXXX" information brochure. My questions have been answered to my satisfaction.

I agree to participate in this research on an entirely voluntary basis. I retain the right to revoke this consent without having to provide any reasons for my decision, and am aware that I am entitled to discontinue the experiment at any time. If my research results are used in scientific publications or made public in any other way, they will be fully anonymised. My personal information may not be viewed by third parties without my express permission.

I have been screened for all potential risk factors involved in this type of research, and have answered the relevant questions truthfully.

I have signed a separate form granting permission to contact my doctor in the event that MRI scans yield any incidental findings that could be of interest to me.

If I need any further information on the research , now or in the future, I can contact researcher XXXX (phone number: 020-525xxxx or email xxxx@uva.nl, xxxx, 10xx XX Amsterdam, room xxx) or an independent physician, namely Dr XXXX (phone number + 31 (0)20-xxxxxxx, email xxxx, address XXXX).
If I have any complaints regarding this research, I can contact the secretary of the Ethics Committee of the University of Amsterdam's Faculty of Humanities, commissie-ethiek-fgw@uva.nl (phone number: 020-525 xxxx; Spuistraat 210, 1012 VT Amsterdam).

Signed in duplicate:

…… ……
Name of participant Signature

'I have explained the research in further detail. I hereby declare my willingness to answer any further questions on the research to the best of my ability.'

…… ……
Name of researcher Signature

Statement of consent

There is a minute chance that the scans made as a part of the research will establish that you have a form of brain damage, such as a brain tumour. If this should occur, we will send the MRI of your head to a radiologist, who will check our findings. If the radiologist confirms our findings, the information will be passed on to your doctor. If you do not agree to this procedure, you may not take part in the research. If you do agree to the procedure, you will have to sign a consent form, stating the name and address of your doctor. We should point out that the laboratory assistant and research leader are not trained to detect all forms of brain damage, and that some forms of brain damage cannot be identified by the MRI scan we will be taking of your head.

I hereby grant permission to contact my doctor if the MRI scan identifies any form of brain damage.

The name of my doctor is:……..
Location of my doctor's office (address, where appropriate):……..

…….....

Name of participant
Signature
Date

c) Parental informed consent form for research involving children

'I hereby declare that I have been clearly informed about the nature of the research and the methods used, as described in the [above, where appropriate] information brochure. My questions have been answered to my satisfaction.

I hereby declare that I am authorised to sign the consent form for my child's participation in the aforementioned research.

I hereby grant voluntary consent for participation in this research by the child under my custody. I retain the right to revoke this consent without having to provide any reasons for my decision, and am aware that my child is entitled to discontinue the experiment at any time. If the research results of the child under my custody are used in scientific publications or made public in any other way, they will be fully anonymised. The child's personal information may not be viewed by third parties without my express permission. [Consent may be given here for the broader use of audio and video recordings, by means of a separate signature.]

If I need any further information on the research, now or in the future, I can contact researcher XXXX (phone number: 020-525XXXX or email XXXX@uva.nl, xxxx, l0xx XX Amsterdam, room XXX).
If I have any complaints regarding this research, I can contact the secretary of the Ethics Committee of the University of Amsterdam's Faculty of Humanities, commissie-ethiek-fgw@uva.nl (phone number: 020-525 xxxx; Spuistraat 210, 1012 VT Amsterdam).

Signed in duplicate:

……
Name of participant (child)

……	……
Name of guardian	Signature

'I have explained the research in further detail. I hereby declare my willingness to answer any further questions on the research to the best of my ability.'

……	……
Name of researcher	Signature
……	Date

d) Passive informed consent

You hereby consent to your child's participation in this research on an entirely voluntary basis. You retain the right to revoke this consent without having to provide a reason for your decision. Your child may discontinue the research at any time. If the research results of your child are used in scientific publications or made public in any other way, they will be fully anonymised. Your child's personal information may not be viewed by third parties without your express permission. [There is no option to provide consent for the broader use of audio and video recordings]

If you need any further information on the research, now or in the future, you can contact Dr XXXX (phone number: 020-525xxxx...; email: xxx@uva.nl; Spuistraat xxx, l0xx XX Amsterdam, room xxx). If you have any questions or complaints regarding this research, you can contact the secretary of the Ethics Committee of the University of Amsterdam's Faculty of Humanities, commissie-ethiek-fgw@uva.nl (phone number: 020-525 xxxx; Spuistraat 210, 1012 VT Amsterdam).

The school board of your child's school consents to your child's participation in this research, and will be offering its full cooperation. If you object to your child's participation in this research, you may inform the school board (phone number of contact person XXXX) or responsible University of Amsterdam researcher (Dr XXXX (phone number: 020-525xxxx...; email: xxxx@uva.nl) by XXXX at the latest. You will not be required to give a reason for your decision, and your objection will be accommodated unconditionally.

Afterword

Medical Ethics Review Board (METC) or Ethics Committee (EC)?

Some procedures designated as standard research by the EC may not be (fully) subject to the Medical Research (Human Subjects) Act (*Wet medisch-wetenschappelijk onderzoek met mensen*, or WMO). This mainly concerns research involving the use of medical equipment, such as EEG, MRI or other psychophysiological measurements, and more or less invasive procedures or the showing of emotional images. According to national and international professional literature and common procedures, participants are exposed to a negligible risk in all these cases. Nevertheless, opinions tend to differ on whether and to what extent such research is subject to the WMO. In practice, the Ethics Committee will regularly seek the advice of an accredited METC or the CCMO when determining whether or not research is subject to the WMO.

Legal aspects

According to Article 1.17 of the Collective Labour Agreement of the Dutch Universities (version: 1 September 2007 through 1 March 2010), the UvA is always responsible for any damage to third parties caused by UvA staff while carrying out their professional duties. The research assessed by the EC is always conducted under the supervision and responsibility of a UvA employee; liability for damages to third parties is thus adequately covered. The UvA is insured against such damages. Article 1.8, paragraph 2 is also relevant in this regard: employees are required to carry out their duties to the best of their ability and follow all instructions issued by or on behalf of their employer. In accordance with Article 1.17, paragraph 3, failure to comply with regulations on the ethical review of scientific research may be regarded as reckless behaviour by the employee.