**Application for Ethics Review**

**EK\_Q\_EN Version 1.1 (Revised: 02.2022)**

Ethics Committee (Internal Review Board)

Friedrich Schiller University, Jena, Germany

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# User Instructions

* The Ethikkommission, referenced as “**EK**”, functions as Internal Review Board (**IRB**) for university research at FSU.
* EK can only review research information as provided by scholars – who have responsibility for identifying salient ethical issues. This questionnaire aids the process of identifying those issues.
* Questions are based upon general experience of academic research review. Though the attempt is to be comprehensive, the questions below may not adequately capture the nature of ethical issues in the specific research being reviewed. Thus, please treat the questionnaire as a reflective process, and use available text boxes to fully describe issues, even if your descriptions diverge from the questions themselves.
* The questionnaire contains redundancies, which are intentional. Please answer all questions fully. However, you may answer questions with reference to previously answered questions. When doing so, please make references using question number, not page number.
* If appropriate, please attach relevant documents as addenda to this application. If this is done, please list the document in section 9.
* Please answer all questions by filling the coloured textboxes and marking  appropriate checkboxes:
* If a checkbox is marked, all items grouped below it should also be addressed
* Items marked with a star (\*) must be answered/checked

# General information

**Full Title of the research under review**

Investigating US memory specificity in Evaluative Conditioning: A “who said what” approach

**Name and contact details of investigator(s)**

|  |  |
| --- | --- |
| Principle Investigator | Dr. Karoline Bading |
| Cooperating Scholars | Dr. Jérémy Bena |
| Supervising Scholar (For research leading to university degree: Doctoral, MA, BA) | Prof. Dr. Klaus Rothermund |
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| Phone Number(s) | 01638432506; 03641-945118 |

**Abstract/summary of research. Please note salient issues for ethics review process**

Click here to enter text.

# Basic information about proposed research

## Has the research already been reviewed by the EK?

No

Yes. Please indicate below and state whether present application is for a basic review or for an amendment of existing review.

Provide information here, indicate nature of previous review and reference numbers.

## Research start date and end date

Time period covered by ethics review: 01.06.2023 – 31.12.2023

The data collection will take place at some point in this period. Exact dates for the start and end of data collection cannot be provided while the present research has not been approved by the ethics committee.

## Funding

### Describe the funding for proposed research

University-based research, no outside support

Public/Government funding (EU, DFG, BMBF, Humboldt, …)

*If ethics review is intended for grant proposal, please indicate*.

Industry or other forms of funding

*Indicate cooperation, funding levels, potential bias, or interest conflict*.

### How will be the results be available?

Openly available in standard academic publishing process

Restricted access, not intended for publication

If restricted, please explain here.

# Framework of proposed research

## Aim of research

The aim of the research is to investigate whether EC procedures produce memory representations that can be estimated by the “Who said what” MPT model introduced by Klauer & Wegener (1998). Moreover, we want to test whether individual MPT parameter estimates predict EC effects on a rating measure.

## Methods

The study will be run online. Participants will be recruited via Prolific. Participants will have to look at stimulus pairings. Later on, they will be asked about their memory for the stimulus pairings. They will also be asked to rate some of the stimuli.

## Subject/participants’ actions within study

In the first part of the study, participants will undergo a learning procedure. In this learning procedure, participants will look at pairs of fictitious nonwords and (positive or negative) images.

In the second part of the experiment, participants in the “memory task first” condition will perform a memory task followed by an evaluation task. Participants in the “evaluation task first” condition will perform the same two task, but in reversed order.

In the memory task, participants will be presented with the previously paired “old” nonwords as well as with “new” nonwords that had not been part of the learning procedure. For each nonword, participants will have to indicate whether the nonword is “old” or “new”. Whenever, a nonword is classified as “old”, participants will be presented with a list of images (4 positive, 4 negative). Participants will have to click on the image with which a given nonword was paired with during the learning procedure. If the cannot remember the image, they are supposed to take a guess.

In the evaluation task, participants will be presented with all “old” and “new” nonwords. For each nonword, participants will have to express their evaluation on a rating scale ranging from 1 (very negative) to 8 (very positive).

At the end of the experiment, participants (in both conditions) will be asked whether they paid attention during their participation and whether they responded seriously. Participants will have the chance to comment on the study, receive a debriefing and will then be redirected to Prolific to receive their compensation.

## Procedure of the study/study design

### Please describe the study design

The study will follow a 3 (nonword type: positively paired vs. negatively paired vs. unpaired) x 2 (Task order: memory task first vs. evaluation task first) mixed design. The first (second) factor will be manipulated within (between) participants.

### Does the study include deception/illusion to generate results?

No (If no, please continue to next section, 2.5)

Yes. Please answer the following questions.

a) What information is given to the subjects?

Click here to enter text.

b) Why is deception necessary? Explain justification and why alternatives are not sufficient instruments?

Click here to enter text.

c) Which form of deception/illusion is used?

Information is withheld.

False information is given.

d) Explain special arrangements (during recruitment of participants, the wording of the participation information, …)

Click here to enter text.

e) Is it reasonable to expect that the deceptive information influences potential participants’ willingness to participate?

No

Yes

Click here to enter text.

f) Does study contain aspects that may induce elevated physical or psychological strain?

No

Yes. Please describe appropriate care provided to address potential stress:

Click here to enter text.

g) Formalities for studies using deception:

*Please note information that must be provided in sections 5. and 6.*

h) Please describe timing and method of debriefing. *Ideally the participants are informed in writing and the process is standardised.*

Click here to enter text.

i) Checklist for required debriefing after deception:

Debriefing is offered to every participant (not solely available on demand).

All participants are informed thoroughly about the study.

The role of the participant as an "associate” is emphasized.

Information is given about the true goal of the study.

Information is given why a deception was necessary.

The background of the deception is explained.

A request for forgiveness is expressed.

The subject has the possibility to ask further questions.

If the participant feels aggrieved because of the style of the study: Support is provided (e.g.: invitation to group meetings with other affected persons, personal talk)

## Does the study expose subjects to any burdens or risks?

*If even only minimal burden or risk involved, please use sections below to describe a) nature of burden or risk, b) how it is being addressed, c) why it is acceptable, and d) outweighing benefits. Burdens and risks can be physical, psychological, social, environmental, and economic. They can be relevant for individual participants, groups, or wider society.*

### Burdens: Does the study expose subjects to any burdens?

No

Yes. What kind of burdens exist for subjects?

**Physiological** (e.g., blood extraction, saliva extraction, administration of drugs, placebos, invasive/non-invasive measurements) *Describe below.*

Click here to enter text.

**Psychological** (aversive stimuli, i.e., negative experiences) *Describe below.*

Participants will see positive and negative images during the learning procedure and during the memory test. Some people might experience looking at the negative pictures (showing e.g. a cockroach, a bloody knife or the site of a plane crash) as unpleasant. Due to this, participants are warned of these potentially disturbing images before consenting to participate in the study.

### Risks: Indicate whether subject participation involves any risks (physical, psychological, social, or economic). If so, please describe the specific risk(s) and measures planned to minimize and deal with risk.

**No risks** could be reasonably expected from the study participation.

**Physical risk potential** – (e.g., pain, injury, sense impairment, …) *Explain below.*

**Psychological risk potential** - (e.g., feelings of sadness, anxiety, grief, negative self-appraisal, and self-esteem) Explain below. Appropriate measures include: oversight and surveillance, exclusion of vulnerable groups, the offer of social support for the subject, debriefing concerning the study purposes and study procedure).

**Social risk potential** - (e.g., concerning social status) *Explain below.*

**Economic risk potential** - (e.g., relevant to insurance) *Explain below.*

Please describe risk and actions to minimize and deal with study risk. If aftercare is provided, please indicate how and when it is given.

Participants may feel unwell because of looking at the negative images (see above). Participants are warned of these potentially disturbing images before consenting to participate in the study. We do not provide aftercare.

### Is insurance for subjects needed?

No

Yes. Explain below.

Explain the insurance coverage for subjects.

### Do the objectives and methods of the study merit consideration regarding ratio of risk/burdens and potential benefits?

Please make a statement concerning the distribution of risks and benefits from the perspective of participating subjects.

Participants might have an unpleasant experience when looking at the negative images. However, participants are warned of these images before consenting to participate in the study. They can also abort the experiment whenever they wish without any negative consequences (and are informed of this option before consenting to participate). Finally, participants will earn 8 Euro (around 10 Pounds) per hour, depending on the exact duration of the experiment.

## Does the study include an intervention (treatment) which provides either a) potential benefit and/or b) removal of harm? (For example: provides a treatment with potential to heal, cope, reduce pain, treat disability)

*Researchers have moral responsibility to treat participants in intervention studies fairly. Prior to study conclusion, research findings may indicate a responsibility to modify the study. For example, study findings may indicate unambiguous benefits of the intervention, rendering it unethical to deprive intervention benefits from the control group. The following statements are mostly relevant for longitudinal studies and demonstrate that researchers understand and respect the underlying ethical issues related to the principle of justice.*

No. The study involves no intervention with potential of either benefit or harm.

Yes. Please describe intervention element, and potential for benefit/harm.

Click here to enter text.

If study demonstrates unambiguous benefit before the study is finished, and the benefit is non-trivial for participant well-being, the intervention benefit will also be provided to the control group. \*

Care will be taken regarding subject-screening advertisement. This clause is important for intervention studies including interventions/treatment for illnesses, disabilities, or studies providing potentially significant life benefits. Potential subjects may have heightened expectations that make them vulnerable. Thus, care must be taken to avoid taking unfair advantage of vulnerable persons with study advertisements or claims regarding benefits from study participation. Limitations must be clearly stated. \*

## What kind of information from the participants is needed/requested?

During the memory task, we will record whether a nonword is classified as “old” vs. “new”. If a given nonword is classified as “old”, we will also record participants’ response in the second memory task asking to identify the previously paired image. At the end of the experiment, we will record participants’ response to the questions of whether they paid attention and whether they responded seriously. If participants make a comment about the study, this will also be recorded.

Finally, Prolific will provide us with information on age and gender of each participant.

@JEREMY: IS THIS CORRECT? WHAT ABOUT FIRST LANGUAGE, NUMBER OF PREVIOUS SUBMISSIONS ON PROLIFIC, PROLIFIC APPROVAL RATE – ARE THEY ALSO INCLUDED IN THE DATA FILES?

## Is the study done entirely within the EU? Is the country in which the study is performed a member of the EU?

*From Horizon2020 (6.2): “Any use of local resources […] must show respect for cultural traditions and share benefits (i.e., also benefit local participants and their communities, involve local researchers – as equal partners – and respond to local research needs).”*

Yes. Please continue with section 3.

No. *Please answer questions below:*

### Please provide cultural context and describe local ethical considerations. Explain whether a local ethics review is required.

Click here to enter text.

### How will the researcher(s) deal with local culture, circumstances, and social practices?

Click here to enter text.

### Will there be a collaborative partnership with the local community for purposes of performing the study?

Yes. Please explain. Make sure to address how decision-making capacities as well as responsibilities are shared.

Click here to enter text.

No. Please explain why.

Click here to enter text.

### Will study provide tangible benefits for local study population?

No.

Yes. Please describe fair distribution of benefits to participants and/or local community:

Click here to enter text.

### Is the ratio of potential social or economic risks for the local community and the knowledge gained from the study favourable? Please address specifically whether the knowledge gained will also benefit the local community.

Click here to enter text.

### Some studies require an expert report on local ethics. Is consultation with an ethics committee chair recommended? Has it already been done?

Click here to enter text.

# Data Protection

## What kind of data is collected or otherwise processed?

*Data protection law poses different requirements to different categories of personal data, i.e., the processing of personal data revealing ethnicity, political opinions, religious or philosophical beliefs, … is subject to even stricter rules. For technical questions, please refer to the Research Data Management Helpdesk at:* [*https://www.researchdata.uni-jena.de/en*](https://www.researchdata.uni-jena.de/en)

Please list all categories of personal data involved in the research.

* Age
* Gender
* First language
* Number of previous submissions on Prolific
* Prolific approval rate

## How is the data processed?

Please explain how the data according to 3.1 is processed.

We will calculate the mean and standard deviation of participants’ age.

We will calculate the relative frequencies of the different genders.

First language is required to be English for all participants and will therefore not be analysed.

We will not analyse the number of previous submission on Prolific or the Prolific approval rate.

Data on age and gender will be included in anonymized data sets that we will upload to a repository on the homepage of the open science framework.

@JEREMY: WOULD YOU AGREE?

## On what basis is personal data processed?

Data protection law requires that any data processing is based either on the consent of the study participant or on a legal basis. Consent is obligatory whenever the data processing constitutes an intense interference with the fundamental right of a data subject to the protection of personal data.

Consent: please note the consent form you intend to use and submit copy of consent form as “Addendum” to this application.

Click here to enter text.

Other: Please name the legal provision upon which you base your research.

Click here to enter text.

## Is the data protection secure?

*Data protection law requires that any data processing must be fully transparent and comprehensible for the data subject (See: GDPR, Art. 13). Collected personal data must be protected by adequate IT measures, including protection against unauthorized or unlawful processing and against accidental loss, unintentional destruction, or accidental damage.*

Please explain the technical and organizational measures taken for data security. In particular explain the IT used and the measures taken for anonymization or pseudonymization.

Click here to enter text.

# Subject Sample

## Sample recruiting process

### Please describe the sample recruiting process.

Click here to enter text.

### Inclusion criteria and exclusion criteria: Is inclusion in study limited in any structurally significant way? (For example: economic situation, student status, language ability, age range, pregnancy status, gender, …)

No

Yes. Please explain:

Click here to enter text.

### Please describe the way this study is advertised (for example: public advertising).

Click here to enter text.

## Was a subject sample from database used?

No

Yes. Please describe characteristics of the database:

Click here to enter text.

### Has the data protection officer of database given consent?

No

Yes. Please provide data protection officer’s name and contact information. \*

Click here to enter text.

## Characteristics of the subject sample

### Please describe the subject sample (target group, number, sex, age,…)

Click here to enter text.

### Are subjects chosen from a specific demographic group that is considered vulnerable?

*For example: pregnant, human foetuses or neonates, under 18, over 65, health-care facility patients, presenting sub-optimal health-characteristics, from region of conflict, refugees, low income, incarcerated, students, employees, ...*

No. Study participants are not from a vulnerable group.

Yes, because study participants are unable to give consent:

Click here to enter text.

Yes, because study participants are from a vulnerable population (from conflict region, refugees, cognitive disabled, persons that are incarcerated, persons with low income, students, employees). Please describe vulnerability of subject population:

Click here to enter text.

Yes, because study participants are under the age of 18: See section 4.5 below.

Yes, because study participants are patients under health supervision:

In outpatient care

In hospital setting

Patients presenting disease (for example: under medical attention for psychological issue, addiction, disability):

Click here to enter text.

Patients otherwise presenting sub-optimal health characteristics: physical, emotional, or otherwise:

Click here to enter text.

Patients with strong dependence upon institutions – where this dependence could impinge upon freedom to participate in study (for example patients with cancer):

Click here to enter text.

### If the study includes subjects from vulnerable population

1. How is the vulnerability ascertained, and how are subjects protected?

Click here to enter text.

1. Explain the need for a study including individuals belonging to the vulnerable population and how the study provides benefits for study participants (risk-benefit reasoning if relevant):

Click here to enter text.

## Ability to give consent

Are all subjects over 18?

Yes. Please answer paragraph 4.4.1

No. Please answer paragraph 4.4.2

### Questions for researchers when all subjects are over 18:

#### Do subjects participate that (maybe) cannot give their consent?

No. Please continue with Subsection 4.5

Yes

#### From which group do these subjects come?

Adults that are temporarily unable to give consent (for example: patients after polytrauma, concussion, stroke, traumatic or septic shock, delirium)

Adults that are permanently unable to give consent (for example: patients with dementia)

#### Why is it necessary to include these persons (that are unable to give consent)? Could the study be done with adults that can give informed consent themselves?

Click here to enter text.

#### Examination of the ability to give consent

a) Is an examination of the ability to give consent done (by a physician, other)?

Yes \*

No

b) How is the ability to give consent tested?

Click here to enter text.

c) To assess the ability to give consent the following points are tested individually (if one of the points is not fulfilled then the person is unable to give consent):

The person understands a specific situation (aim of the study, procedure, impairments, risks, alternatives). \*

The person can make decision based on understanding, process, and evaluation. \*

#### Participation of the subjects that are unable to give consent

a) A person that is unable to give consent is not allowed to participate unless one of these points is fulfilled. Which of the points is fulfilled in the proposed research?

Individual benefit

The study wants to improve the health of the group to which the person belongs.

The study cannot be realised with persons that can give informed consent.

The study has a low risk and minimal physiological/psychological stress.

b) Formalities: Which of the following points is fulfilled?

The conservator (gesetzlich ermächtigter Vertreter) has given consent (the conservator must have the permission to decide in the area of “science”) & the conservator is only allowed to give informed consent when the participation “meets the will of the participant”.

How is conservator informed about the study?

Click here to enter text.

How does the conservator give consent?

Click here to enter text.

The person themselves has given consent at a time when the person was able to give informed consent.

c) How is the subject treated that is unable to give consent?

Is approval sought for study participation? *Please describe*

Click here to enter text.

What happens when the person does not give approval?

Click here to enter text.

### Questions for researchers when some/all subjects are under 18 years old:

#### How old are the children?

Under the age of 11 (no ability to reason; cannot give consent)

Between 11 and 13 years (the researchers must examine if the children have the ability to grant consent)

Between 14 and 17 (ability to grant consent is assumed)

#### Participation of the subjects that are unable to give consent

a) A person that is unable to give consent is not allowed to participate unless one of these points is fulfilled. Which of the points is fulfilled in the proposed research?

Individual profit or benefit

The study wants to improve the health of the group to which the person belongs.

The study cannot be realised with persons that can give informed consent.

The study has a low risk and minimal physiological/psychological stress.

b) Formalities

Subjects’ information form is given to the parent(s) \*

Consent is given from both parents (in case that children are the subjects). \*

Age-appropriate information is provided in printed format. \*

Under-18 children express understanding of study and willingness to participate. \*

Under-18 children are instructed that they can withdraw from study at any time. \*

#### Why is it necessary to include this group of persons under 18? Could the study be done with adults that can give informed consent themselves? Describe age-appropriate measures used to protect study participants.

Click here to enter text.

## Gender and Diversity Issues: Is research in any way relevant to matters of gender, ethnicity, or diversity?

No elevated relevance to for gender, ethnicity, or diversity

Yes. Please explain how, and why:

Click here to enter text.

## Is an internet-based data collection performed?

No

Yes. If yes, how are the inclusion and exclusion criteria ensured?

Click here to enter text.

*A contact person must be available for the subjects.*

## Do subjects receive compensation?

No. Please continue with section 5

Yes. Please answer following questions:

### Which groups of subjects get which form/kind of compensation and how much? And describe appropriate ratio between compensation and effort.

Click here to enter text.

### If children participate: Please describe their age-appropriate compensation:

Click here to enter text.

### Does the compensation impact who participates, or risks undertaken?

Click here to enter text.

### Data protection

Receipt for the money is saved separately from the gathered data. \*

### Equity

1. Do groups of persons differ in their compensation?

No

Yes. Please explain which groups and why?

Click here to enter text.

1. Do subjects know about the form/kind of compensation prior to the beginning of the experiment?

Yes \*

No

1. Does compensation involve a raffle? (A raffle is not direct compensation, but ticket with a chance for winning a prize in a future competition.)

No

Yes, and subjects are informed about the number of the raffle gifts (e.g., of gift cards) and the probability of winning a prize. \*

### If a subject declines to complete the experiment:

*Participants have, in principle, a right to abort their participation without any disadvantages. Please comment below if the participant’s incomplete participation impacts their compensation.*

Subject has the right to abort the experiment at any time without any disadvantages.

Partial or no compensation given depending upon subjects’ level of participation.

Please explain compensation strategy and reasons for partial or no compensation.

# Subject information form

## Please check that the following points are included in subject information form:

The subject information form is a separate document from the informed consent document. \*

The aim and process of the study are described. \*

The admission and exclusion criteria are described. \*

The subject’s time investment for the experiment is mentioned. \*

Possible advantages for subject’s participation are described. \*

Clearly stated is the participant’s right to quit the experiment at any time without negative consequences. \*

Data protection measures are assured. \*

Protections and limitations of access to study data are clearly stated. \*

There is a clear statement regarding how personal data will be utilized. \*

There is a clear statement regarding how study data will be published. \* (anonymised/pseudonymised)

There is a clear statement regarding study-participation compensation or reward. \*

Statement includes the kind of compensation/reward. \*

Statement includes conditions necessary to receive compensation/reward. \*

There is a clear statement regarding whether the study provides insurance. \*

If insurance is provided for study participants, the nature of insurance is stated. \*

Contact details of a contact person are given (for questions of the participant). \*

The subjects are informed that their participation is voluntary. \*

The subjects are informed that they have the possibility to ask questions. \*

Data protection - The following points are communicated:

How data is saved \*

How long the data is saved \*

Collected data is saved so that a direct link between the participant and data is no longer possible (anonymisation or pseudonymisation) \*

## Is pseudonymised data used?

No

Yes. Please confirm following points:

Subjects are informed that the code list is deleted after the data acquisition. \*

The exact date of the deletion is indicated („by no later than the \_\_.”). \*

The subjects are made aware that a deletion of his/her data is only possible until specified date (deletion date). \*

If the code list should be stored longer, then the subjects are asked for an additional informed consent. \*

## Is research an intervention study?

No, this is not an intervention study.

Yes, this is an intervention study. Please confirm following points:

Information about the method of allocation to the different groups (for example: randomisation) are given. \*

The word “randomisation” is explained.

Information about alternative treatment options is given.

(As the circumstances require) information about the experimental character of the treatment is given.

(As the circumstances require) information about cost takeover is given.

If two more or more equally effective interventions are tested, then the subjects are informed in which group they are.

If the participation within the experimental group leads to advantages for the participating people, then information is given:

The offers that are available for the control group. Which are not available?

Alternatives that do exist if a potential participant does not participate or if the participation is cancelled prematurely.

Information about who bears costs for implemented intervention? (Do the participants have to pay for it? Is it refunded from some institution?)

## When deception is used:

No, deception is not used.

Yes, deception is used. Please confirm following points:

The subject is informed that at the beginning of the experiment not all the information can be given and that a full education will be given after the experiment \*

The subject information form doesn’t contain wrong information \*

# Consent form – Checklist

## Please confirm the following points regarding the consent form.

The consent form is a separate document from the subject information document. \*

The consent form is given to the subjects in written form, or access to downloadable copy of the form is available for online studies. \*

Each subject receives two consent forms to sign. \*

One version is kept by examiner; the other version is for the subject. \*

The full title of the study is listed on the consent form. \*

The consent form includes a department letterhead with address, contact person for study, telephone number, and e-mail address. \*

## Is video footage/audio recorded?

No

Yes, and additional consent for the video footage/audio recording is requested. \*

## Does the research entail potential physical risks (especially: MRI, TMS, genome-wide analysis)?

No

Yes, and potential risks are clearly stated in consent form. \*

## Will study data be published and re-used in the context of open science?

No

Yes. Please confirm following points:

Participants are informed regarding the how their data will be maintained in anonymised/pseudonymised formats in an open repository for use by third parties. \*

Participants are informed that the specific reason and the purpose of the re-use of the data is not known at the moment (the law concerning the re-use of data differs between different states; make sure that in your state it is acceptable to formulate the purpose of the re-use broadly). \*

The subject is asked for consent to re-use their data. \*

If no consent is given, a re-use is not done. \*

## Is a re-contacting planned (for further data collection or other reason)?

No

Yes, and subjects are asked for consent to a re-contacting. \*

## When deception is used:

No, deception is not used.

Yes, deception is used. Please confirm following points:

Consent form contains the phrase: “I was informed that I’m not fully enlightened about all aspects of the study at the present moment. I will be informed after the end of the experiment.” \*

The consent document contains only true information. \*

The consent is obtained during the debriefing (because due to the deception, a full consent could not be obtained before the experiment). \*

The participant is asked about consent after being fully informed about the purpose of the study and knows that a deletion of personal data is still possible. \*

The consent does not refer to the participation but to the use of the collected data   
(For example: “I give consent to the usage of the collected data”;   
“I exercise my right to delete my collected data). \*

## Is the subject covered by university insurance?

Yes

No, and subject is informed that the university bears no insurance responsibility.

# Reporting results and incidental findings

## Are results reported to the participants?

No. Please continue with subsection 7.2

Yes

### Which results are reported to the subjects?

Click here to enter text.

### How are these results reported to the subjects?

Click here to enter text.

### Are there possible consequences associated with reporting?

Click here to enter text.

### When are the results reported?

Click here to enter text.

### Are the results only reported if the subject agreed to the feedback and has given consent?

Yes \*

No

## Are incidental findings possible?

No. Please continue with section 8

Yes

### What kind of incidental findings are possible?

Click here to enter text.

### Communication

1. Does the subject participate in a study within a treatment context?

Yes, and the person is informed about incidental findings. \*

No, and the subject is asked for his/her consent regarding information about incidental findings in the consent form. \*

* If the subject agrees to the feedback:

The person is asked if feedback is wanted if intervention options exist (e.g., delayed language acquisition, delayed cognitive development, dementia, suicidality). \*

The person is asked if feedback is wanted because of individual interest. \*

In the consent it is made clear who gets the feedback (only the parents, only the children, also the children, can the children decide that they don’t want the parents to know the feedback). \*

1. How are the participants informed about incidental findings?

Click here to enter text.

# Voluntariness and knowledgeability are ensured

Which of the following points apply to the process of information and consent prior to the beginning of the experiment?

The subject information form is given to every subject. \* (exception: see 4.7)

All subjects must sign the consent form. \* (exception: see 4.7)

The subjects can withdraw from the experiment at any time without any consequences. \*

There is the possibility for the subjects to ask questions. \*

Enough time is scheduled for addressing subjects’ questions before start of study. \*

Subject participation is clearly voluntary. \*

# Documents checklist

## Standard documents included

Research proposal (grant proposal, dissertation proposal, anything official submitted for research permission or funding)

Consent form \*

Subject information form \*

Every other form that is handed over to the subject \*

External documents (previous or partner ethics approvals, letters of cooperation indicating ethics-relevant matters, letters of invitation from outside contexts where research will take place, ethics review of the original data-collection if data is re-used) \*

## Other documents included

* List all documents here.

Click here to enter text.

Place and date, name in block letters

Click here to enter text.

Signature of the applicant (digital signature is possible)