*Application for ethical approval at DTU Compute’s Institutional Review Board*

**Project title:**

Principal investigator: <Name, position>

Other investigators: <Name, position>

(include affiliations)

Date:

Contact person: <Name, email, address>

**Page limit = 7 pages! (for the ethics application protocol, excluding subject information and consent forms, including the title page)**

1. **Project motivation, background, and hypotheses**
	1. **Background**
	2. **Purpose**

**1.3 Hypotheses**

1. **Study methods**
	1. **Measurement techniques**

*(describe all the measurement techniques employed in the study, i.e. EEG, ECG, eye-tracking, questionnaires, etc)*

* 1. **Experimental design/setup**

**2.3 Procedure**

**2.4 Statistical considerations (sample size, statistical analyses)**

1. **Participant info**

*(inclusion/exclusion criteria, age and number of participants, recruitment procedure, reimbursement if any, debriefing)*

1. **Ethical considerations (informed consent, side effects, risks, inconveniences)**

*(discuss any ethical issues including informed consent – how will it be obtained, risks and safety concerns and side-effects, any deception used, etc.)*

1. **Data protection & handling**

*(Specify how the data will be handled, how it will be anonymised – pseudo- or fully, including the procedures to accomplish this)*

1. **Finances**

The initiator of this project is ….
The project has received funding donated to … by …. (XXX DKK).
The research group has no financial conflicts of interest.

1. **Dissemination of results**
2. **Future applications and implications of the proposed research**
3. **Study period (data collection only)**

The data collection for the project will start in mm yyyy and end in mm yyyy.

1. **References**

**Subject information letter (EN)**

**Dear participant,**

In this letter we will inform you about the purpose of the experiment and the procedures. It is important that you read the letter carefully. If you have any questions, do not hesitate to contact us (*contact info*) for clarification.

 **Your rights as participant**

*Your participation in this experiment is voluntarily.* This means that you can leave the experiment at any point in time without consequences for yourself, and without having to give a reason. However, in accordance with GDPR rules, your research data collected before you withdraw your consent will not be deleted. We will ask you to give informed consent to participate in this study, once you have been informed about the experiment.

**Purpose of the research project**

**Data storage and handling**

**Methods**

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**Informationsbrev til deltageren (DK)**

**Informed consent form (EN)**

*[to be filled out by experimenter before the experiment]*

Experiment: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*[to be filled out by the participant before the experiment]*

I confirm that:

* I was satisfactorily informed about the study concerned both verbally and in writing by means of the subject information letter.
* I have had the opportunity to put forward questions regarding the study and that these questions have been answered satisfactorily
* I have carefully considered my participation in the experiment
* I participate of my own free will

I agree that:

* My data will be acquired and stored for scientific purposes as mentioned in the subject information letter in **pseudo/fully** anonymized form
* My data may be shared / will not be shared ….

I understand that:

* My participation is voluntary, and I have the right to withdraw from the experiment at any time without having to give a reason
* Should I withdraw from the experiment, my research data collected before my withdrawal may still be used for research purposes
* My privacy is protected according to Danish law and European guidelines (GDPR; EU 2016/679)
* My consent will be sought every time I participate in a new experiment

I give my consent to take part in this experiment:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Full name Date of birth

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date, Place Signature

**Erklæring om informeret samtykke (DK)**

*[udfyldes af forsøgsleder inden eksperimentet]*

Eksperiment: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_