FORSØGSPROTOKOL

Projekttitel

(Project title in Danish)

Forsøgsansvarlig

(Responsible for the experiment)

*Name, title*

*Research center/group*

Department of Health Science and Technology

Aalborg University

Fredrik Bajers Vej 7D3

9220 Aalborg

Phone:

Email:

Klinisk ansvarlig

(Clinically responsible doctor)

*Name, title*

*Research center/group*

*Affiliation*

*Address*

Phone:

Email:

* A clinically responsible doctor is required when the research methods are invasive and/or “dangerous” (“dangerous” methods include, e.g., transcranial magnetic stimulation or laser stimulations on the skin)
* The clinically responsible doctor must be a Danish medical doctor with a B authorisation or a specialist doctor.
* CV and authorisation number of the doctor must be forwarded to the committee together with the protocol.

Projektgruppe

(Project group)

*Name, title, affilliation*

Kontaktperson *– fill in if another person than the Forsøgsansvarlig*

(Contact person)

# Experimental Protocol

## Background

An introduction to the present research project with a short survey of the pertinent literature. Based on this description the committee must be able to decide whether it is scientifically reasonable to do the present project and if the project is based on sound hypotheses.

The description also is to enable the committee to reach a decision on whether this project is justified: meaning can it lead to therapeutic improvements and improvements in the health of the general populace?

If a similar study has been performed previously, then it has to be described including the reason for reproducing the study.

### Strategy for Literature Search

A short description of the strategy for the litterature search within the area (stating search string (MeSH), databases, number of references found and the selection of these). It may be stated that meta-analyses, Cochrane reviews are available, and in this case the conclusions of these.

*Proposal for standard text:*

The basis of the study has been found among peer-reviewed articles, publicly available material and Aalborg University’s own research. XX articles were found and xx references used (please see the section List of References) for this study which form the basis for the research within xxx.

The literature has been found by reviewing of the search engines: xxxx. The following search words were used in combinations for review of the literature: xxx.

Only studies with interest within human research have been used and the studies have been produced within the last 10 years.

## Purpose

A general description of the purpose of the project and its hypotheses.

### Purpose of Sub-project 1

The purpose and hypothesis of sub-project 1

### Purpose of Sub-project N

The purpose and hypothesis of sub-project N

## Subjects

This section is to include the following information:

* Number of subjects
* Age
* Inclusion and exclusion criteria
* Use of biological material from a research bio-bank
* How are subjects recruited?

*Proposal for standard text:*

For this study we wish to recruit xx healthy volunteers through notices at Aalborg University, on [www.forsog.dk](http://www.forsog.dk), on Facebook and in the press (notice is attached). The following inclusion and exclusion criteria will be used:

### Inclusion

Healthy men and women in the age 18-80 years

### Exclusion

* Pregnancy
* Drug addiction defined as the use of cannabis, opioids or other drugs
* Previous neurologic, musculoskeletal or mental illnesses
* Lack of ability to cooperate

NB: Only mention HIV, hepatitis and other contagious illnesses as exclusion criteria if there is an actual reason for this and if the participants are tested for these illnesses in connection with the screening.

## Design and Methods

A description of the experimental design and the measuring methods. The ethics committee requires that this section allows the committee to evaluate the scientific standard of the project and to evaluate whether the project will result in new valuable knowledge.

In this section it also has to be clearly stated if invasive measurement or surgical interventions are performed on the participants in the study.

If placebo is used, it also has to be stated clearly.

## Research Bio-bank

If biological material is taken from the subjects and stored for analysis, it makes up a research bio-bank, unless the samples are analyzed and destroyed immediately after being taken.

This section should include the following information:

* What is taken out and the quantity
* The purpose of the research bio-bank
* The duration of the storage period
* Whether the material is passed on/exported – and if so to which countries
* What happens to the biological material after analysis (destruction, anonymization (i.e. without codes) or storage in a bio-bank for later research)

## Risks, Side Effects and Disadvantages

A description of the side effects, risks and disadvantages of participating in the experiment. If there are any, it has to be described how likely they are to occur.

If the project includes injections, the description of side effects should include information on risk of bleeding in the muscle and precautionary measures taken to avoid infections

Pain, fear and other foreseeable risks and disadvantages have to be minimized in the experiment, and security measures to prevent these have to be taken and described.

## Statistics

Description of the statistics to be used for evaluation of the results of the project and how they are used to that end.

Furthermore, this section should include power calculations.

## Ethical Considerations

This section is to include a thorough risk/benefit assessment of the experiment and an assessment of predictable advantages for the subjects, for others and for the research. The section is to prove that risks and side effects are compensated for by the advantages of the research.

Do not mention “normal clinical standards” in this section.

Please note that the Committee has a strong focus on this section at present.

*Standard text for pain trials:*

The study will be reported to ClinicalTrials.gov.

## Insurance

*Standard text:*

The subjects are covered by the Danish Patient Compensation Association (Patient­erstatningen).

## Placebo/Control Treatment

*Explanation of placebo/control treatment, if any.*

## Personal Data

*Standard text:*

Data will be stored after termination of the project. These data can only be used for the interpretation of this project and will therefore not be of interest to third party.

Data are stored in accordance with the stipulations in the data protection rules and other relevant legislation.

The project is registered through internal registration in the Article 30 Register of AAU.

*It is extremely important to observe the rules of “Databeskyttelsesforordningen” (The General Data Protection Regulation) on data security and the rights of the subjects, whose data are registered, are fulfilled.*

*This means that rules on transfer of data to third countries are to be observed by the person responsible for the project.*

*See more about the requirements for health scientific research projects (in Danish):*

[*https://www.datatilsynet.dk/emner/forskning-og-statistik/saerligt-om-sundhedsomraadet/*](https://www.datatilsynet.dk/emner/forskning-og-statistik/saerligt-om-sundhedsomraadet/)

*Please also note that special requirements apply for clinical trials with medicinal products, clinical testing of medical equipment and obligatory safety supervision of medicinal products and medical equipment.*

## Information from Medical Charts

If you wish access to the medical charts of the subjects, the following must be mentioned:

* Which information you wish to obtain
* What will the information be used for

## Project Economy

This section is to describe the economy of the project, including:

* Who has initialized the project?
* Names of commercial and non-commercial funding sources
* The amount of money that each funding source has provided for the project
* If the person responsible for the project has any economic ties to private companies, foundations or other parties which may have an interest in the project.

The experiment has been initiated by xxx(name), xxx(title), xxx(affiliation), and is financed with DKK xxx from xxxx. The amount is administered by Department of Health Science and Technology, Aalborg University.

None of the researchers have financial interest in the experiment.

## Compensation to Subjects

*Proposal for standard text*:

The subjects will receive DKK xxx per hour/experiment session as compensation for their participation in the experiment. The amount is liable to tax and will therefore be reported to the Danish tax authorities as B-income.

Subjects who do not complete the experiment will receive proportional compensation for the time spent.

## Publishing of Results

*Standard text:*

All results of the project will be published regardless of the outcome of the project.

## Time Schedule

Time schedule for the project

## Guidelines for Oral Information and Informed Consent

Standard text:

### Summoning Potential Subjects

When potential subjects address the contact person, the following should be stated:

* That it is a request for participation in a scientific research project
* The purpose of the project
* That participation is voluntary and that the subject can withdraw from the project at any time without consequences
* That the potential subject has time to consider his/her participation before giving consent to participation in the project and that the potential subject is welcome to bring a family member or a friend to the information meeting. The potential volunteer will receive the leaflet “The Rights of a Trial Subject in a Health Scientific Research Project”/ "Forsøgspersonens rettigheder i et sundhedsvidenskabeligt forskningsprojekt" which includes information on confidentiality, right of access to documents and right to complain.
* That the material “Information for Participants”/”Deltagerinformation” will be forwarded by mail/e-mail to the potential subject in order for him/her to know more about the project before the information meeting.
* Finally, time for the information meeting is arranged

### The Information Meeting

The information meeting is held in a quiet room where it is possible to have an uninterrupted conversation. Coffee/tea/soft drink may be served. The information meeting is held by the person responsible for the project or a senior researcher who has been authorized to do the information.

The meeting is to include the following information/questions:

* Participation is voluntary and the subject can withdraw from the project at any time without consequences
* The subject has time to consider his/her participation before giving consent to participation in the project, and the subject is welcome to bring a family member or a friend to the information meeting.
* The subject is asked whether he/she wants a family member/friend to be present at the meeting.
* The purpose of the experiment is presented, and it is explained how the experiment is performed. The “Information for Participants”/”Deltagerinformation”, which has been sent to the potential subject in advance, is the starting point for the information meeting.
* The subject is asked if he/she is healthy or whether he/she has an infectious disease.
* The subject is asked whether he/she is a Danish citizen. If the answer is no, he/she is asked if he/she has a valid work permit.
* The leaflet “The Rights of a Trial Subject in a Health Scientific Research Project”/ "Forsøgspersonens rettigheder i et sundhedsvidenskabeligt forskningsprojekt" is handed over. It is explained that it includes information on confidentiality, right of access to documents and right to complain.
* The subject is asked whether he/she has read “Information for Participants”/ ”Deltagerinformation”. If this is not the case, we will ask the subject to read it.
* When it has been ensured that the subject has read the “Information for Participants”/”Deltagerinformation”, he/she is asked whether he/she has questions about the experiment.
* After this a demonstration is given in the lab; measuring equipment and its use is presented to the subject.
* It is underlined that participation is voluntary, and that the subject has time to consider his/her participation (please note that The National Committee on Health Research Ethics recommends 24 hours of deliberation time)
* Again it is underlined that participation is voluntary and that the subject can withdraw his/her consent at any time without consequences.
* The subject is informed that if he/she does not need time to consider the participation, the consent can be given at the information meeting.
* Time/place for the experiment is agreed.
* Finally, information about the contact person of the experiment is given (it is shown to the subject that the name and contact details appear from the “Information for Participants”/”Deltagerinformation”) and it is informed that this person can be contacted at any time if further questions should arise.

# List of References