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## Project: Emotional Metamemory

The Institutional Review Board at DNC has discussed the project at its meeting on 14 August 2019. The board asked for more material, which was submitted on 1 October 2019.

Based on the submitted material, the committee has taken the following decision.

### Decision:

The project is approved.

The approval applies to the notified locations, its notified investigators in Denmark and for the specified project period.

The approval is valid until 1 February 2020 and is based on the following documents:

- Metamemory Study Protocol
- Emotional Metamemory Info for participants
- (DANISH EDITION) Emotional Metamemory Info for participants
- Emotional Metamemory ICF-DA-1.0
- Emotional Metamemory IRB-Application –rev1.0\_signed MA

Department of Clinical  
Medicine - Center of  
Functionally Integrative  
Neuroscience

Leif Østergaard  
Professor, director

Dato: 4. oktober 2019

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Web: [au.dk/leif@cfin](http://au.dk/leif@cfin)

Case number: DNC-IRB-  
2019-006

Afs. CVR-nr.: 31119103

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### Changes:

If significant changes to the protocol material are made during the implementation of the project, these must be reported to the committee in the form of protocols changes or amendments. The project may only resume after approval from the committee.

Protocol changes and amendment must be submitted to the secretariat at DNC with the project's assigned notification number.

Significant changes include changes that may affect subjects' safety, interpretation of the scientific documentation on which the project is based, and implementation or management of the project. For example, there may be changes in in- and exclusion criteria, project design, number of subjects, project procedures, duration of treatment, effect parameters, changes regarding the investigators or locations and changes in the written information material to the subjects.

If new information causes the researcher to consider procedure changes or project termination, the committee shall be notified immediately.

### **Side Effects and Unexpected Incidents:**

#### **Ongoing reporting**

The committee must be informed immediately if suspected serious, unexpected adverse incidents or serious incidents occur during the project.

The report must be accompanied by comments on any consequences for the experiment. Only side effects and incidents occurred in Denmark have to be reported. Notification shall be made no later than 7 days after the sponsor or the investigator has received knowledge of the case.

Reporting must be made to the chair of the Committee and the secretariat at DNC with the project's assigned notification number.

#### **Completion:**

Within 90 days after the completion of the project the investigator must send a final report to the committee. The project is considered as completed when the last subject is completed.

Reporting must be made to the secretariat at DNC with the project's assigned notification number.

If the project is not initiated, the committee must be informed of the reasons.

The Committee requests a copy of the final research report or publication. We note that there is a duty to publish both negative, positive and inconsistent test results.

The following committee members participated in the meeting:

Professionals

- Leif Østergaard (Chairman)

- Elvira Brattico
- Mads Jensen

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Technicians


- Torben Lund

Lay people

- Hella Kastbjerg
- Henriette Vuust

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Yours sincerely



Leif Østergaard