Appendix

Ref. 2013/1265-31/2

DECISION



'STOCKHOLN'

Applicant: Danderyd Hospital Authorised representative: Karin Malmqvist Project: EFFECTS - Establishing the effect and safety of fluoxetine in the case of stroke a randomised placebo-controlled study of 1,500 patients. Researcher who will carry out the project: Veronica Murray

At the meeting of 21 August 2013, the board decided that the applicant should add to the case in accordance with the following:

The board requests that the applicant adds to the case in accordance with the following:

1. "Ethics Committee" should be changed to the Ethical Review Board.

2. There should be a safety monitoring board to evaluate any side-effects during the course of the study. Is there such a board?

3. The participant information should begin with information about the fact that the participant is included in a study.

The board handed over to the scientific secretary to decide on the case once the addition has been made.

Since the applicant has submitted the requested additions, the scientific secretary decides as follows.

DECISION

The board approves the research.

On behalf of the board [signed] 30 September 2013 Anders Björkman Scientific secretary

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