

Simon Hyttel-Sørensen
Rigshospitalet
Department of Neonatology
Juliane Maries Vej 6
2100 København Ø
Denmark

Committees on Health Research
Ethics, Capital Region

Blegdamsvej 60, 1. sal, opgang
94A11
2100 København Ø
Denmark

Department Health Research and Innovation
Telephone +45 3866 6395
Mail vek@regionh.dk

Journal no.: H-21034369

Date: 7 October 2021

H-19027423 - SafeBoosC-III Safeguarding the brain of our smallest children - an investigator-initiated, pragmatic, open label, multinational, randomized phase III clinical trial evaluating treatment based on near-infrared spectroscopy monitoring versus treatment as usual in premature infants

The Committees on Health Research Ethics in the Capital Region of Denmark hereby confirm that above research project is approved, and registered to be completed by 30 April 2022.

Generally, an approved project is valid throughout the accepted period, and a regular confirmation of the approval does not take place. Unless otherwise stated, the approval includes all documents listed in the approval letter. Extension of a study might be approved when applied for later.

On 04 October 2021 the Committees on Health Research Ethics in the Capital Region approved follow-up study *SafeBoosC-III two-year follow-up (Safeguarding the brain of our smallest children)* after submission of a substantial amendment.

According to Danish law all health research, taking place in Denmark, must be approved by an Ethical Committee and must comply with Danish legislation. Please note, that "GCP" and "ICH-GCP" rules are only partially implemented in Danish law.

For additional inquiries, please contact the Secretariat for the Committees on Health Research Ethics in the Capital Region at +45 3866 6395 or by e-mail vek@regionh.dk

Kind regards,

A handwritten signature in dark ink, appearing to read 'Marie Skovgaard', written in a cursive style.

Marie Skovgaard
Office assistant

The Secretariat for The Committees on Health Research Ethics in the Capital Region
of Denmark

Copy send to:

- Gorm Greisen, Marie Isabel Skov Rasmussen