SOP: tasks for principal investigator before start of follow-up

Version	Author(s)	Date	Changes	Approved by
1.0	Marie Isabel S Rasmussen	01.07.21	Initial version	Gorm Greisen

The following tasks must be completed to take part in the follow-up study

1. **Ethics approval**

   The protocol has been approved by the Steering Committee, and can be submitted to the local ethics review board. It may be possible to submit it as an addendum to the SafeBoosC-III trial, which may speed up the process in some countries.

   National coordinators will obtain ethics approval for their own NICU first and coordinate ethics approval processes in their own country. In some countries, one approval will cover all NICUs involved in the trial, while in other countries, each NICU must obtain their own ethics approval.

2. **Blinded assessor**

   Delegate the review of health care records and outcome assessment to a competent colleague who will be the co-investigator performing the eCRF entries. It is important that the co-investigator can be blinded to the group allocation in the SafeBoosC-III trial. Please provide us with the contact information of this person.

3. **Blinding procedure**

   To ensure that outcome assessment is blinded, the principal investigator and co-investigator from each NICU must develop a local blinding procedure describing the workflow. This should be sent to marie.isabel.skov.rasmussen@regionh.dk and approved before local study commencement.

Furthermore we encourage PIs to ensure that the contact information, ideally e-mail addresses of the parents, is maintained so that links to the web-based platform with the PARCA-R questionnaire and the health and development questionnaire can be forwarded to the parents when necessary.