PROOF OF QUALIFICATION OF THE STUDY SITE WITH DESCRIPTION OF THE CLINICAL TRIAL TEAM

1. Study title:	ALBINO - Effect of Allopurinol in addition to hypothermia for hypoxic-ischemic brain injury on neurocognitive outcome
2. Protocol code of the sponsors: H2020-PHC-18-2015-667224 EudraCT-Number:	2016-000222-19
3. Coordinating investigator:	Prof. Dr. Axel Franz Center of Pediatric Clinical Studies Calwerstraße 7, 72076 Tübingen, Germany

Information on the qualification of the study site

4. ID of the clinical trial site:

5. Study site's main focus of treatment (e.g. neonatal intensive care unit level III)

6. Has the study site already conducted other clinical trials?

◯ No ◯ Yes

If yes, number, which medical indication / phase / year:

Study Title / Indication	Phase	Year/s

Current number of clinical trials:
Current number of clinical trials in the same patient population:

7. Are there any competitive trials being conducted in the study site?

◯ No ◯ Yes

If yes, according to which criteria the patients are being allocated to the different trials:

Capacity:

8. Average number of patients being treated at the study site for the medical indication relevant for this study within one year:

9. Number of patients planned to be recruited at the study site for this study:

Infrastructure of the study site:

10. Facilities and equipment of the study site with regard to the planned clinical trial:
(e.g.: complete facilities according to the recommendation by the medical professional society)
→

11. Emergency care guaranteed by:
(e.g.: medical advice around the clock by shift work and intensive care unit on the premises)
→

Information on the clinical trial team:

12. Name and professional title of the principal site investigator (PSI):

13. Name and professional title of deputy site investigator:

14. Additional staff (Physicians, Intensiv care nurses, study nurse)

Number/ Qualification	Tasks
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With her/his signature, the <u>Principal Site Investigator</u> confirms

1) **the accuracy and completeness of the information**

<u>and</u>

2) **that she/he is aware of the following tasks and obligations:**

Tasks of the investigator
- **organization of the clinical trial team**
- **delegation of tasks to other members of the clinical trial team and its documentation**
- **organization of rules of representation**

Furthermore, the investigator must ensure
- **that the members of the clinical trial team are informed on all study-relevant aspects and receive or know about all relevant study documents**
- **the information flow within the clinical trial team**
- **that new members of the clinical trial team get the necessary instructions and guidance**
- **the compliance with all relevant laws, Good Clinical Practice, the trial protocol and if applicable of the clinical trial agreement**

<u>and</u>

3) **that she/he will ensure that all members of the clinical trial team have the necessary knowledge and qualifications to exercise her/his study-relevant duties and that she/he has been/or will be thouroughly instucted in the study and the study documents.**

Date: (DD.MM.YYYY) **Name:**

Signature: _____

With her/his signature, the <u>Deputy Site Investigator</u> confirms,

that she/he will assume responsibility and all obligations of the investigator in case of her/him being prevented. This also includes vacation replacement.

Date: (DD.MM.YYYY) **Name:**

Signature: _____

<u>Declaration of consent by the Medical Director of the Study site</u>

I agree with the conduct of above mentioned trial in my hospital/department/clinic

Date: (DD.MM.YYYY) **Name:**

Signature: _____

<u>Please print these pages and send them after signing via fax to the number:</u>
<u>0049 7071 - 294471</u>