Responsibilities of The National Investigator

Contents

This document outline the responsibilities of The National Investigator in HOT-ICU. It can be used as a general guideline or if requested in the form of a contract if signed by Sponsors representative Bodil Steen Rasmussen and National Investigator.

1. National approval from Authorities

It is the responsibility of The National Investigator to apply all relevant authorities and to achieve approval of the HOT-ICU Trial from National Authorities prior to trial start.

2. National contact for national authorities

Should there be any need of national authorities wanting to contact Sponsor or Sponsors representative, the National Investigator will act as middle-man/woman.

3. Recruiting clinical sites on a national level

It is the responsibility of the National Investigator to recruit clinical sites on a national level.

4. Provide national approvals and documents to national clinical sites

It is the responsibility of the National Investigator to provide national approvals and documents for HOT-ICU to national clinical sites, whereas it is the responsibility of the site investigator to apply and achieve approvals specific for the hospital to which the site is affiliated.

5. Patient insurance

It is the responsibility of the National Investigator to request a patient insurance if national laws prescribe it and to provide an estimate of overall national recruitment on which the insurance contract should be based on. It is the responsibility of CRIC to provide such an insurance contract.