Responsibilities of The National Investigator

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This document outlines the responsibilities of The National Investigator in CRIC affiliated trials. It can be used as a general guideline or - if requested – as a contract between Sponsors representative and National Investigator if signed.

Center for Research in Intensive Care (CRIC) assist the trial teams with non-clinical administrative tasks. Please feel free to contact CRIC office by e-mail contact@cric.nu, CRIC Project Manager, Birgit Agerholm Larsen by e-mail bal@cric.nu or call CRIC office +45 35 45 71 67 for administrative support.

# National approval from Authorities

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

# 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.

# Recruiting clinical sites at a national level

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

# Provide national approvals and documents to national clinical sites

It is the responsibility of the National Investigator to provide national approvals and documents (i.e. national medicine agencies, ethic committees) for the trial to all 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.

# 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 in collaboration with National Investigator.

# GCP

It is the responsibility of the National Investigator to assist CRIC with organizing local monitoring in terms of contact information to local/national organizations or providers of such services. CRIC will then handle all administrative contact and contract with the provider of the monitoring services, taking advice and feedback from National Investigator into consideration.

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