The National Coordinating Investigator's Role

1. Identification and recruitment of local participating centres

National Coordinating Investigators (NC) will advertise the study among colleagues in other hospitals with the POSE study protocol and information available on the POSE study website.

- NC will make all efforts to get at least as many as possible centres per country.

- If NC identify and recruit local participating centres in his/her country, they will ask the centre to fill in the "POSE Registration Form" (available on the https://pose-trial.org). Interested centres will be acknowledged on receipt of the form by the POSE study team. The POSE study team will inform the NC about this registration.

2. Assistance with the translation of study documents - upon needs

- NC will help to translate the Patient Information Sheet and Informed Consent Forms from the English version into the patients' language. Translation of the protocol (or protocol summary) is optional as many Ethics Committee (EC) or Institutional Review Board (IRB) don't require it.

- NC will keep the POSE study team informed on the progress of the translation process into their patients' own language.

- Some countries will not perform translation as their language is already available. (e.g. German translation to be used in Austria or French version to be used in Belgium) or if their local EC/IRB has waived the informed consent process.

3. Ethical and regulatory (if applicable) approvals

The NC will ensure that all local necessary ethical and regulatory approvals are obtained before the start of patient recruitment in the respective national centres.

- At a minimum, the local Ethics Committee/Ethical Review Board approval is required. The protocol, information sheets and informed consent forms will need to be submitted by each centre to their EC (and to local health authorities when necessary).

- In case a single national EC approval is valid for several centres, NC will ensure the approval letter specifies the names of each participating institution and clinician. A sentence including “this approval is valid for the study conduct in any centre of the country” is also valid.

- Each centre must return the "Approval Documentation Coversheet" (available under Documents on the website: https://pose-trial.org) to the POSE study team, together with their proof of Ethics approval/judgement/notification and copy in the NC. The NC will check that the coversheet is appropriately filled in and that the relevant patient documents (if appropriate) have been submitted and approved or if the local centre received a waiver. It is crucial that each centre understands and reports what is required in terms of patient information and consent.

- There is no budget from the POSE study team to support local EC or regulatory submission costs.

4. Assistance and training

The NC will assist and train the local Principal Investigator and monitor the conduct of the study according to good clinical practice (ICH-GCP guidelines).

5. Data cleaning process

The NC will help to coordinate data cleaning in their countries.

- The NC will be informed at the end of the study by the POSE data management about the data entry/completeness status and the number of queries related to their country.

6. Co-authorship

The NC will be listed as a co-author in upcoming POSE publications, for details see study protocol.