

## **Guideline: The local Principal Investigator's role**

### **1. Contact person**

Local Principal Investigator is the main point of contact for that Institution and is responsible for communication with the POSE study team on the mandatory steps below. The Local Principal Investigators must have all the necessary requirements to perform the study and are expected to complete the trial successfully at their centre.

### **2. Site registration**

Local Principal Investigator will register the centre by filling in the "Registration Form" (available on <https://pose-trial.org>). This registration form includes the pre-study questionnaire, regarding the centre specific information.

### **3. Ethics Committee (EC) and/or Institutional Review Board (IRB) and/or Regular Authority (RA) (if applicable)**

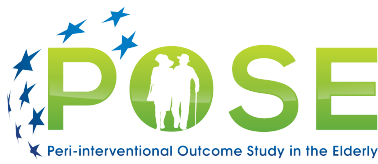
Local Principal Investigator has to ensure, that local Independent Ethics Committee (EC) and/or Institutional Review Board (IRB) and/or if applicable Regular Authority (RA) approvals are obtained, before initiation of the study.

The National Coordinating Investigator of the respective country will support the local Principle Investigator with the regulatory affaires.

Local Principal Investigators should not initiate research involving human subjects without obtaining first a written informed consent from each subject, unless they have received explicit EC and/or IRB approval to waive a written informed consent.

If a single national EC approval is valid for several centres, National Coordinating Investigators will ensure that the approval letter mentions the names of each institution and clinician. If the national approval is applicable for several centres in a country it will be sent out by several centres but each time with an 'Approval Documentation Coversheet' filled in specifically by the various Institutions.

If **no** national EC approval is required for several centres, the Local Principal Investigator's role is to complete the necessary local submission and return the following documents to the POSE study team (E-mail: [astevanovic@ukaachen.de](mailto:astevanovic@ukaachen.de) or Fax: +49241-80-3335766):



"EC judgment and/or Ethical Approval (or regulatory)" (can be in local language)

**and**

A signed "Study Approval Document Cover sheet". Both documents must be returned to the POSE study team at least one week before the start of patients' inclusion in order to receive the log-in access to the eCRF website.

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

#### **4. Electronic case report form (eCRF) access**

The Local Principal Investigator may request to the POSE study team two additional sets of log-in details for the electronic CRF (eCRF) to allow local collaborators to assist with data entry. Please send the institution name, family name, first name and e-mail address of the people needing access for data entry to the POSE study team.

If the centre reasonable requires more sets of log-in details, the Local Principle Investigator may request it at the POSE study team.

#### **5. Study period**

The Local Principal Investigator will choose a time-span of 30 days within the 8 months recruiting period.

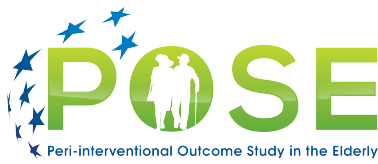
The Local Principal Investigator will inform the POSE study team at least 8 days in advance of the planned study recruitment for its Institution.

#### **6. Oversee and monitor local research group**

The Local Principal Investigator is responsible for ensuring that Good Clinical Practice (ICH-GCP guidelines) are followed by the staff working in the study for that Institution (ICH GCP Guidelines <http://www.ich.org>). Staff working on the study at the institution should be on the POSE Study Task Delegation Form (available under Study Documents on the website: <https://pose-trial.org>).

#### **7. Integrity of data collection**

The Local Principal Investigator is responsible for ensuring integrity of data



collection. By assigning the data on eCRFs, the Local Principal Investigator confirms the data integrity.

### **Ensure timely completion dataset:**

The Local Principal Investigator will make sure that all subjects' data is entered no later than 4 weeks after the 30 day follow up visit of the last subject.

The Local Principal Investigator will coordinate local data cleaning process: POSE data management will contact the Local Principal Investigator if there are queries related to their institution's data.

- Data queries are sent to the Local Principal Investigator by the POSE data management (DM) team via the Data Clarification Forms (DCF).
- Data Clarification Form (DCF) is a list of questions to clarify discrepancies. It is an important step towards creating a clean dataset suitable for statistical analysis of the clinical trial outcome.
- The Local Principal Investigator has to respond to the DCFs by returning the DCF back to DM within 1 week.

### **8. Communication with the National Coordinating Investigator (NC)**

The Local Principal Investigator will communicate with NC whenever there is a doubt regarding a process that is 'national' e.g. Ethics process and/or applicable existing translation for study documents.

### **9. End of study Reporting Form**

The Local Principal Investigator is responsible for returning the "End of study reporting form" confirming who are the local staff members with sufficient involvement in the trial in order to be listed on the publication list of collaborators or to receive a certificate of participation. The form is available under Documents on the website: <https://pose-trial.org>.