**FLO-ELA Trial: Feasibility questionnaire for potential sites**

|  |  |  |  |
| --- | --- | --- | --- |
| Date completed: |  | Completed by (name/role): |  |
| Site name: |  |
| Suggested principal investigator (PI):NameRoleEmail addressTelephone number |  |
| Main contact / research nurse:Name:RoleEmail addressTelephone number |  |
| R&D main contact:NameRoleEmail addressTelephone number |  |

|  |  |  |
| --- | --- | --- |
| **Criteria** | **Comments** | **Check** |
| **Clinical Aspects** |
| Does the Principal Investigator have any comments to make about the trial? For example with regards safety, ethical acceptability, scientific soundness? |  | [ ]  Yes [ ]  No  |
| Are the procedures documented in the protocol consistent with your hospital standards of care? |  | [ ]  Yes [ ]  No  |
| **Investigators/Site Experience** |
| Does the Principal Investigator have previous experience with:1. Clinical research?
2. Study population?
3. Trial intervention?
 |  | [ ]  Yes [ ]  No [ ]  Yes [ ]  No [ ]  Yes [ ]  No  |
| How many studies/trials is this hospital currently recruiting from this patient population? |  | Total open & enrolling: \_\_Total in follow-up: \_\_ |
| How many working hours per week do the research team estimate they have available for the FLO-ELA trial? |  | \_\_\_\_ hours / week |
| Have the site staff received relevant regulatory training (eg Good Clinical Practice / Research Governance)? |  | [ ]  Yes [ ]  No  |
| Does the site anticipate that training staff in GCP and other regulatory requirements will be a problem? What resources are in place to do this? |  | [ ]  Yes [ ]  No  |
| **Trial Population and Recruitment** |
| What is your anticipated likely recruitment rate, having reviewed inclusion & exclusion criteria? |  |  \_\_\_\_ patients / week |
| Are there any circumstances that may be expected to affect recruitment? |  | [ ]  Yes [ ]  No  |
| **Facilities and Equipment** |
| Would the site be able to use cardiac output monitoring equipment (which will be provided where required) if relevant training was provided? |  | [ ]  Yes [ ]  No  |
| Does the site have any cardiac output monitoring equipment available on site? If Yes:What brand(s) – approx. number of eachWhat approximate level of usage currently? |  | [ ]  Yes [ ]  No  |
| Does the site have adequate, secure storage for study records (e.g. Consent Forms)? |  | [ ]  Yes [ ]  No  |
| Are archiving facilities available to the site? |  | [ ]  Yes [ ]  No  |
| **Electronic Data** |
| Do site staff have experience with the National Emergency Laparotomy Audit data entry portal? |  | [ ]  Yes [ ]  No  |
| Are there local policies in place for the storage, transfer and security of data? |  | [ ]  Yes [ ]  No  |
| Does the site have support for data entry? *NB FLO-ELA does not require CRFs, just NELA data entry and reporting of withdrawals/SAEs/protocol deviations* |  | [ ]  Yes [ ]  No  |
| **Monitoring/Audit** |
| Are study staff willing to allow the FLO-ELA management team access to the medical records and source documents to ensure compliance with good clinical practice and adherence to the protocol? |  | [ ]  Yes [ ]  No  |