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| **Effects of Advanced Trauma Life Support ® Training Compared to Standard Care on Adult Trauma Patient Outcomes: A Cluster Randomised Trial** | | |
| *Site Location:* | |  |
| *Site name/ hospital:* | |  |
| *Batch & Site no.:* | |  |
| *Name of PI:* | |  |
| *Date of initiation* | |  |
| **Site Staff Present** | | |
| Name | Position | |
|  |  | |
|  |  | |
| **Project Team/Sponsor/Other Representatives Present** | | |
| Name | Role | |
|  |  | |
|  |  | |
| **Type of visit (select all that apply):**  On-site  Online  Other (specify)  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |

*In the following table please tick Yes, No or Not Applicable and add comments.*

*Insert comments on each item, providing information specific to the site. Also comment on issues and actions for follow-up. Please assign a number (1, 2 etc.) to the items in the “Actions and Follow-up” table below.*

| **The following items were reviewed/discussed during the initiation visit:** | **Yes** | **No** | **N/A** | **Comment or Follow up item #** |
| --- | --- | --- | --- | --- |
| 1. **Protocol** | | | | |
| * 1. Project objective and design |  |  |  |  |
| * 1. Inclusion/exclusion criteria |  |  |  |  |
| * 1. Protocol procedures and schedule of events; other protocol requirements |  |  |  |  |
| * 1. Protocol adherence; protocol deviations and violations |  |  |  |  |
| * 1. Protocol amendment procedure |  |  |  |  |
| 1. **SOP** | | | | |
| * 1. Enlist all site-specific SOP |  |  |  |  |
| * 1. List the SOP which needs to be shared with the sites |  |  |  |  |
| 1. **Recruitment of Participants** | | | | |
| * 1. Site recruitment target and timelines |  |  |  |  |
| * 1. Recruitment/screening method; enrolment procedure |  |  |  |  |
| * 1. Recruitment material (Hospital / Medical records) and requirement (including IEC approval) |  |  |  |  |
| 1. **Informed Consent** | | | | |
| * 1. Informed Consent process and documentation requirements |  |  |  |  |
| * 1. Informed Consent Storage |  |  |  |  |
| 1. **Source Documents** | | | | |
| * 1. Source document requirements (Medical records, patient notes) |  |  |  |  |
| * 1. Monitor access to source documents (including electronic data) |  |  |  |  |
| * 1. Maintenance of source documents |  |  |  |  |
| 1. **Data Collection** | | | | |
| * 1. Case Report Form and completion guidelines, including eCRF use submission procedure |  |  |  |  |
| * 1. Query process, requirements and timelines |  |  |  |  |
| * 1. requirements for electronic data and medical records |  |  |  |  |
| 1. **Safety Reporting Procedure** | | | | |
| * 1. Safety Reporting Process, recording in source documents, reporting to GC (if applicable) and follow-up requirements |  |  |  |  |
| * 1. Safety Reporting requirements |  |  |  |  |
| 1. **Facilities and Equipment** | | | | |
| * 1. High speed internet |  |  |  |  |
| * 1. Desktop   2. Storage of study documents   3. Secure storage for study device. |  |  |  |  |
| 1. **Additional Investigator’s Responsibilities** | | | | |
| * 1. IEC approval and communications |  |  |  |  |
| * 1. Monitoring |  |  |  |  |
| * 1. Audit and inspection |  |  |  |  |
| * 1. Sponsor publication policy |  |  |  |  |
| * 1. Financial aspects of the project |  |  |  |  |
| 1. **Site Staff** | | | | |
| * 1. The investigator and site staff are aware of their responsibilities in ICH GCP |  |  |  |  |
| * 1. CV and MRC |  |  |  |  |
| * 1. Investigator Signature and Delegation of Duties Log |  |  |  |  |
| * 1. Project-specific training, including GCP training |  |  |  |  |
| 1. **Investigator Site File** | | | | |
| 1. ISF index reviewed and contents complete |  |  |  |  |
| 1. Protocol |  |  |  |  |
| 1. Informed Consent form |  |  |  |  |
| 1. Site Clinical Trial agreement |  |  |  |  |
| 1. Retention and archiving of project documents (including source documents) |  |  |  |  |
| 1. **Other** | | | | |
| * 1. Other: specify |  |  |  |  |

**Documents collected during this visit:** none

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**Documents filed in ISF during this visit:** none

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**Pending Tasks:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No.** | **Pending Task** | **Task Assigned to** | **Task completion expected within (days)** |
|  |  |  |  |

**Comments:**

|  |  |
| --- | --- |
| **#** | **Description** |
| C1 | *Add question # that the comment refers to, e.g. Q 4.1 comment…)* |
| C2 |  |
| C3 |  |
| C4 |  |

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| **SIGN OFF** | | | | | |
| **Report Author** |  | **Signature** |  | **Date** |  |
| **Reviewer** |  | **Signature** |  | **Date** |  |
| **Other (if applicable)** |  | **Signature** |  | **Date** |  |