|  |  |
| --- | --- |
| **Effects of Advanced Trauma Life Support ® Training Compared to Standard Care on Adult Trauma Patient Outcomes (ADVANCE TRAUMA): A Cluster Randomised Trial** | |
| *Batch & Site no.:* | |
| *Site name/ hospital:* | |
| *Name of Site Investigator:* | |
| *Date of Close out:* | |
| **Site Staff Present** | |
| Name | Position |
|  |  |
|  |  |
| **Attendees - Project Team/Sponsor & Other** | |
| Name | Role |
|  |  |
|  |  |
| **Date of Final Visit** |  |
| **Visit Type** On-Site  Phone Via email  Other  (specify) | |

*Tick “Yes” if the review item is discussed/finalised with site staff.*

*Tick “No” if the item should have been reviewed but was not done during the visit. If “No” is ticked, comment is required.*

*Tick “NA” if the item is not applicable to the study.*

*If there is comment related to the reviewed item, record the comment in the table below (Comments), and indicate the comment number (C1, C2, etc.) in the right-hand column. Departures from the project-specific site closure guidelines/agenda prepared by the Project Manager should be noted.*

*If there is follow-up activity related to the review item or unresolved monitoring queries, record the issue in Monitoring Issues and Actions Log. Indicate the reference number from the spreadsheet in the comment column.*

| **The following items were reviewed/discussed:** | **Yes** | **No** | **Comment or**  **Follow-up item #** |
| --- | --- | --- | --- |
| **1. IRB/IEC Notification** |  |  |  |
| 1.1 Central IEC notified of site/project closure |  |  |  |
| 1.2 Local IEC/Governance notified of site/project closure |  |  |  |
| **2. Informed Consent** | **Yes** | **No** | **Comment or**  **Follow-up item #** |
| 2.1 All participant consents 100% checked |  |  |  |
| 2.2 All participant consents on file (note where filed) |  |  |  |
| 2.3 All Audio consents are available/ maintained |  |  |  |
| **3. Data Collection** | **Yes** | **No** | **Comment or**  **Follow-up item #** |
| 3.1 All data entered on database or submitted |  |  |  |
| 3.2 All patient follow-up complete |  |  |  |
| 3.3 All data queries closed |  |  |  |
| 3.4 Screening Data entered on database |  |  |  |
| 4.1 All open Safety reports reviewed and finalised |  |  |  |
| 4.2 All Safety reports have been reported to IEC/TMG (as per protocol/ local requirements) |  |  |  |
| 4.4 Other |  |  |  |
| 8.1 Other supplies returned |  |  |  |
| **9. Investigator Site File (ISF)** | **Yes** | **No** | **Comment or**  **Follow-up item #** |
| 9.1 All essential documents up-to-date and on file (at site and TGI) |  |  |  |
| 9.2 All IEC/Governance correspondence on file (at site and TGI) |  |  |  |
| 9.2 Review and retain copies/originals of relevant logs and records. |  |  |  |
| 9.3 Review document storage – accessibility and retention requirements. |  |  |  |
| 9.4 Medical records – accessibility and retention requirements. |  |  |  |
| 9.5 Other |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **10. Protocol Deviations and Violations** | **Yes** | **No** | **NA** | **Comment or**  **Follow-up item #** |
| 10.1 All protocol deviations and violations are recorded and reported as per protocol requirements. |  |  |  |  |
| 10.2 All corrective and preventative actions and issues completed. |  |  |  |  |
| 11. **Discussion with Investigator/Site Staff** | **Yes** | **No** | **NA** | **Comment or**  **Follow-up item #** |
| 11.1 Record retention requirements and responsibilities (including paper and electronic medical records; retention of e(CRF) data). |  |  |  |  |
| 11.2 Financial disclosure (FD) responsibilities, including any changes in FD status (if applicable). |  |  |  |  |
| 11.3 Adverse event follow-up. |  |  |  |  |
| 11.5 Data access and archiving at site/off-site, including the address of where the files will be stored. |  |  |  |  |
| 11.6 Final payment/s. |  |  |  |  |
| 11.7 Publication plans and/or policy. |  |  |  |  |
| 11.9 Provision of final study report and site closure notification to IEC/ or to sponsor. |  |  |  |  |
| 11.10 Relevant future care of study participants. |  |  |  |  |
| 11.11 Other. |  |  |  |  |
| **12. Site deactivation** | **Yes** | **No** | **NA** | **Comment or**  **Follow-up item #** |
| 12.1 All access to electronic systems/database deactivated |  |  |  |  |

**Documents collected during site closure:** none

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Document filed into ISF during site closure:** none

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Comments/Follow-up Items**

|  |  |
| --- | --- |
| **#** | **Description** |
| C1 | *Add question number to which the comment refers, (e.g. Q 4.1 comment….)* |
| C2 |  |
| C3 |  |
| C4 |  |
| C5 |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **SIGN OFF\*** | | | | | |
| **Report Prepared by** |  | **Signature** |  | **Date** |  |
| **Reviewer** |  | **Signature** |  | **Date** |  |
| **Other (if applicable)** |  | **Signature** |  | **Date** |  |

*\*Site Closure Confirmation Letter or email can be sent to site once Site Closure Report has been signed above.*