

## SOS Training and Delegation Log sign-off requirements

**Everyone listed on the delegation log must have completed the Trial Protocol training and GCP training**

| Trial Role/Responsibility            | Who can do this role   | On delegation log?                                     | CV required? | Minimum training required  | Risk assessment and justification   |
|--------------------------------------|--|--|--------------|--|---|
| Screening                            | Any member of the team who has been trained can assess eligibility.  | Do not need to list individuals on the delegation log. | No           | <ul style="list-style-type: none"> <li>- Study team contacts</li> <li>- Eligibility criteria</li> <li>- Targeted screening GCP training</li> </ul>   | These are standard routine assessments made under a standard of care setting for these patients in this patient population, therefore full protocol training is not required. |
| Confirming eligibility               | Must be a medically-qualified doctor. Ideally this individual should sign the Screening and Eligibility CRF to confirm eligibility prior to the patient being enrolled. If this is not possible, the CRF should be signed as soon as possible after the patient has been enrolled. | Do not need to list individuals on the delegation log. | No           | <ul style="list-style-type: none"> <li>- Study team contacts</li> <li>- Eligibility criteria</li> <li>- Targeted eligibility GCP training</li> </ul> | These are standard routine assessments made under a standard of care setting for these patients in this patient population, therefore full protocol training is not required. |
| Performing randomisation             | Any member of the team who has been trained.   | Yes  | Yes          | <ul style="list-style-type: none"> <li>- Data collection guide on how to use randomisation wizard.</li> </ul>  | Restricted user access to database to randomisation wizard only. Enables greater scope for enrolling patients.  |
| Prescribe mannitol/hypertonic saline | Anyone who would usually prescribe mannitol/hypertonic saline  | No   | No           | <ul style="list-style-type: none"> <li>- Eligibility criteria</li> <li>- Targeted drug prescription GCP</li> </ul>                                   | The MHRA have confirmed the drug becomes IMP at point of administration   |
| Administer IMP                       | Anyone who would usually administers mannitol/hypertonic saline  | No   | No           | N/A  | No greater risk than standard care; mannitol and hypertonic saline are both routinely administered in this patient population.  |

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|--|---|-----|-----|---|---|
| <b>Informed consent</b>                      | Doctor or research nurse (if permitted by Trust policy) | Yes | Yes | <ul style="list-style-type: none"> <li>- Full protocol training</li> <li>- Targeted consent GCP training</li> </ul>         | Targeted GCP training enables greater scope for capturing the patient population. |
| <b>Data collection</b>                       | Anyone who has been trained on trial data collection    | Yes | Yes | <ul style="list-style-type: none"> <li>- Full protocol training</li> <li>- Targeted data collection GCP training</li> </ul> | Targeted GCP training enables greater scope for data collection.                  |
| <b>SAE causality assessment and sign off</b> | PI or delegate. (Must be a medically-qualified doctor.) | Yes | Yes | <ul style="list-style-type: none"> <li>- Full protocol training</li> <li>- Targeted SAE GCP training</li> </ul>             | Targeted GCP training enables greater scope for SAE causality assessment.         |