SOS Training and Delegation Log sign-off requirements

Sugar or Salt trial:
Hyperosmolar therapy in traumatic brain injury

Everyone listed on the delegation log must have completed the Trial Protocol training and proportional 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 screen patients for eligibility.	No	No	Targeted training – patient recruitment and trial interventions	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 an individual nominated by the PI that is clinically competent to perform this task i.e. a medically qualified doctor or advanced clinical practitioner (ACCP) only. This individual should sign the Screening and Eligibility CRF to confirm eligibility prior to the patient being enrolled where practical. If this is not possible, the CRF should be signed as soon as possible after the patient has been enrolled.	No	No	Targeted training – patient recruitment and trial interventions	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.	No	No	Targeted training – patient recruitment and trial interventions	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	Targeted training – patient recruitment and trial interventions	The MHRA have confirmed the drug becomes IMP at point of administration

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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.
Informed consent	Doctor or research nurse (if permitted by Trust policy)	Yes	Yes	- Full protocol training - Targeted consent GCP training (if don't already have full GCP training)	Targeted GCP training enables greater scope for capturing the patient population.
Data collection	Anyone who has been trained on trial data collection	Yes	Yes	- Full protocol training - Targeted data collection GCP training (if don't already have full GCP training)	Targeted GCP training enables greater scope for data collection.
SAE causality assessment and sign off	PI or delegate (must be a medically-qualified doctor).	Yes	Yes	- Full protocol training - Targeted SAE GCP training (if don't already have full GCP training)	Targeted GCP training enables greater scope for SAE causality assessment.