Randomisation & IMP preparation for sites who have both unblinded research nurses & unblinded doctor Randomisation is performed by unblinded research nurse

Randomisation

- Blinded research nurse provides the randomisation details to the unblinded research nurse via an unsigned blinded Clinical Trial Request Form (Visit 2)
- Randomisation is performed by unblinded research nurse on TRuST
- The Unblinded Clinical Trial Request Form is generated from TRuST with randomisation allocation and pack IDs

Clinical Trial Request Form

- The Clinical Trial Request Form is generated on TRuST. This must be printed and signed by an unblinded research nurse & unblinded trial doctor
- The unblinded research nurse takes the signed Clinical Trial Request Form to Clinical Trial Pharmacy (CTP)
- The signed unblinded Clinical Trial Request Form must be filed in the PSF

IMP Release

- Clinical Trial Pharmacy release pack IDs on TRuST
- The Clinical Trial Release Form is generated on TRuST and printed
- Pack IDs are released to CTP staff or delegated unblinded team member to prepare IMP infusion
- Page 1 of the Clinical Trial Release Form is signed by CTP staff who released the IMP & the unblinded person collecting the IMP packs for preparation

IMP Preparation

- CTP or delegated unblinded team member prepare IMP with the IV bags provided
- Part of page 2 of Clinical Trial Release Form is completed by the unblinded team member who prepared the infusion
- Infusion is labelled with blinded IV bag labels that have been provided, IV bags are covered with coloured sleeves to protect from light
- The prepared IV bag & page 2 of the Clinical Trial Release Form are given to blinded research nurse to administer infusion
- The last section of page 2 of Clinical Trial Release Form is completed by the blinded person who administered the infusion. This must be filed in ISF.

Randomisation & IMP preparation for sites who have unblinded research nurses but do not have unblinded doctors

Randomisation is performed by unblinded research nurse

Clinical Trial Request Form

- A blinded Clinical Trial Request Form (Visit 2) is completed by blinded research nurse
- The blinded Clinical Trial Request Form is signed by a blinded research nurse & blinded trial doctor
- The blinded Clinical Trial Request Form is provided to the unblinded research nurse

Randomisation

- Randomisation is performed by unblinded nurse on TRuST, entering details from the blinded Clinical Trial Request Form
- Clinical Trial Request Form (unblinded) is generated from TRuST, this should be printed and filed in PSF alongside the signed blinded Clinical Trial Request Form
- The unblinded Clinical Trial Request Form does not require to be signed by a doctor as the blinded form has already been signed

IMP Release

- Clinical Trial Pharmacy release the pack IDs detailed on the unblinded Clinical Trial Request Form
- The Clinical Trial Release Form is generated on TRuST and printed
- Pack IDs & the Clinical Trial Release Form are provided to a delegated unblinded team member to prepare IMP infusion
- Page 1 of the Clinical Trial Release Form must be signed by CTP staff who released the IMP & the unblinded team member who will prepare IMP

IMP Preparation

- CTP or delegated unblinded team member prepare IMP infusion
- Part of page 2 of Clinical Trial Release Form is completed by the unblinded team member who prepared the infusion
- Infusion is labelled with blinded IV bag labels that have been provided, IV bags are covered with coloured sleeves to protect from light
- The prepared IV bag & page 2 of the Clinical Trial Release Form are given to blinded research nurse to administer infusion
- The last section of page 2 of Clinical Trial Release Form is completed by the blinded person who administered the infusion. This must be filed in ISF.

Randomisation & IMP preparation for sites who do not have unblinded research nurses
Randomisation is performed by clinical trial pharmacy

Clinical Trial Request Form

- A blinded Clinical Trial Request Form (Visit 2) is completed by blinded research nurse
- The blinded Clinical Trial Request Form is signed by a blinded research nurse & blinded trial doctor
- The blinded Clinical Trial Request Form is provided to Clinical Trial Pharmacy (CTP)

Randomisation

- Randomisation is performed by unblinded CTP staff on TRuST, entering details from the blinded Clinical Trial Request Form
- Clinical Trial Request Form (unblinded) is generated from TRuST, this should be printed and filed in PSF alongside the signed blinded Clinical Trial Request Form
- The unblinded Clinical Trial Request Form does not require to be signed by a doctor as the blinded form has already been signed

IMP Release

- Clinical Trial Pharmacy release the pack IDs detailed on the unblinded Clinical Trial Request Form
- The Clinical Trial Release Form is generated on TRuST and printed
- Pack IDs & the Clinical Trial Release Form are provided to a delegated unblinded team member to prepare IMP infusion
- Page 1 of the Clinical Trial Release Form must be signed by CTP staff who released the IMP & the unblinded team member who will prepare IMP

IMP Preparation

- CTP or delegated unblinded team member prepare IMP infusion
- Part of page 2 of Clinical Trial Release Form is completed by the unblinded team member who prepared the infusion
- Infusion is labelled with blinded IV bag labels that have been provided, IV bags are covered with coloured sleeves to protect from light
- The prepared IV bag & page 2 of the Clinical Trial Release Form are given to blinded research nurse to administer infusion
- The last section of page 2 of Clinical Trial Release Form is completed by the blinded person who administered the infusion. This must be filed in ISF.