

eISF and Document Box

eISF

The electronic Investigator Site File (eISF) is an electronic folder stored at site, which contains copies of all the TOAST Study documentation. The site team should agree a suitable secure file location for the eISF during site initiation, and use the folder structure and contents provided by the TOAST Study team to organise the TOAST documents. The responsibility of maintaining the eISF is a delegated task, and training should be provided by the site PI (or delegate) to staff members signed off on the TOAST Delegation Log.

The TOAST Study Team will send any amendments to study documentation (once approved by the relevant regulatory bodies) to sites by email, with instructions for new and superseded documents.

Document Box

The TOAST Document Box and contents are provided to the site by the TOAST Study team, following the Site Initiation Visit (SIV). The site team should agree a suitable location to store the Document Box, where it is accessible to all relevant staff.

The Document Box contains copies of all study documents, guidance sheets and other useful information. **Participant data should not be stored in the Document Box.**

The TOAST Study Team will send paper copies of any amended study documents (once approved by the relevant regulatory bodies) to sites by post, with instructions for new and superseded documents.



Site File

An orange ring-binder folder will be provided along with your TOAST Document Box to act as your TOAST Site File. This should be used for:

- Retaining original paper copies of completed Consent Forms, Daily Dosing Logs, Incident Forms and SAE Forms.
- Storing the paper copies of your TOAST Delegation Log and Training Log, to be updated on a regular basis.
- Storing signed '**TOAST for Neonatal Bedside Staff: Study Summary and Preparation, Administration and Disposal of Allocated IMP**'

Send legible electronic copies of consent forms, Incident Forms and SAE forms to the TOAST Study team via the NPEU Document Upload Tool. Updated Delegation and Training logs should be sent to the TOAST Study team via email to toast@npeu.ox.ac.uk

Re-ordering Documents

Please contact toast@npeu.ox.ac.uk if you require resupply of any paper TOAST documents.