

Study Name:	TOAST IRAS number: 1005191	Title:	Treating Oesophageal Atresia to reduce STRICTURE	Page _____ of _____
Hospital:		Principal Investigator:		

Use this legend to complete the "Responsibilities" column on the next page. For each individual listed in the "Full Name" column, enter the letter(s) (e.g. A, C, E) from the legend below that correspond to their study-related responsibilities. If significant protocol related responsibilities that are not already included in the legend, add them in the empty spaces provided below.

Remove/insert additional responsibilities as required

A	Screen patients	G	Data collection / resolution of data queries (OpenClinica)	M	Sign off other staff members on delegation log (following their completion of Bedside Staff Training Sheet) for responsibility 'L' ONLY
B	Confirm Eligibility (*)	H	SAE clinical review/ causality assessment & sign off (*)	N	Sign off other members of staff on delegation log for Responsibilities 'J' and 'K' ONLY
C	Obtain informed consent	I	Prescribe Investigational Medicinal Product (IMP)	O	Sign off other members of staff on TOAST delegation log (*) (**)
D	Randomisation	J	IMP supply/pack management/storage (TOAST randomisation website)	P	All of the above (A-O) (**)
E	Provide study-related training	K	Unused IMP destruction (Pharmacy only)	Q	Other (please specify)
F	Maintain Investigator Site File (ISF)	L	Preparation, administration and disposal of allocated IMP (on the Neonatal Unit)	R	Other (please specify)

Note: * Responsibilities B, H and O can only be delegated to medically trained doctors.

** Responsibilities O and P cannot be undertaken by Associate PIs. Only to be undertaken by those with relevant training, experience and senior level oversight.

The Principal Investigator should sign below during the **Site Close-Out Visit**.

I have reviewed the information on this log and have found it to be accurate. All delegated duties were performed with my authorisation.

Principal Investigator Signature: _____

Site Close-Out Visit Date: _____

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This log should include all relevant study staff and other clinical staff who routinely carry out study procedures or who have specific data collection/interpretation responsibilities.

Add new or replacement staff as appropriate. Please send updated copies to the TOAST Study team (TOAST@npeu.ox.ac.uk)

Note: Please complete the log and obtain the PI's approval before starting study-related responsibilities.

Full Name <i>(Please print)</i>	Role	Responsibilities <i>(Use codes listed above)</i>	Dates of responsibilities		Email address	Appropriate GCP? ✓	Delegated Individual		Principal investigator	
			From	End			Usual Initials	Signature	PI's Signature	Date

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