FLOELA
FLuid Optimisation in Emergency LAparotomy

University Hospital Southampton NHS
NHS Foundation Trust

Training requirements for staff involved in the FLO-ELA trial

A large number of clinical staff members will be involved in caring for patients within the FLO-ELA trial. We have set up the intervention to be deliverable by clinical teams (anaesthesia & ICU trainees or consultants, ICU and recovery nurses) once they are familiar with it.

There is no need for constant research nurse supervision during the trial intervention period, but in the early phase of a site setting up, some training and supervision will be needed until local teams are familiar with the protocol.

In terms of training it may be helpful to think of three tiers of staff involved in the trial – "**recruiters**", "**supporters**" and "**other clinical team members**".

The table below sets out the roles and the training needed.

	"Recruiter"	**"Supporter"**	**"Other clinical team member"**
Typical staff role	Research nurse, trainee or consultant clinician	Wider clinical team including surgeons, ICU doctors, ICU and recovery nurses	Wider clinical team including surgeons, ICU doctors, ICU and recovery nurses
Activity:			
Approach patients, explain trial and give out PIS	Yes	Yes	No
Take informed consent (or use alternative pathway in patients lacking capacity)	Yes	**No**	No
Randomise recruited patients	Yes	Yes	No
Deliver trial intervention	Independently	Independently – if appropriate within their clinical role	Yes - under supervision by a "recruiter" or "supporter"
Report protocol deviations, withdrawals, SAEs	Yes – if given role by PI	No	No
Adjudicate SAEs	Yes – PI or nominated deputy	No	No
Training needed	• GCP • Attend SIV (PI and lead research nurse as a minimum) or review SIV slideset with local research team member	• Review trial-specific "tailored GCP" slideset* • Read randomisation user guide if wish to do this role	[Review trial-specific "tailored GCP slideset" and clinical SOPs if wish to perform intervention without supervision]

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	• Review clinical SOPs • Review other SOPs relevant to delegated duties) • Read randomisation user guide	• Review clinical SOPs • Review other SOPs relevant to delegated duties) • ***Full GCP not required***	
Named on local delegation log?	Yes	Yes	No
Credited on PubMed as local investigator?	Yes (aiming for 5+ recruits per investigator)	No	No

Please contact the FLO-ELA mailbox at admin@floela.org with any queries.

Abbreviations:

GCP – Good Clinical Practice - the international ethical, scientific and practical standard to which all clinical research is conducted.

Training can be found at NIHR Learn (https://learn.nihr.ac.uk/). You will have to login/create a new NIHR Hub account. Once logged in, go to CRN Learning -> Good Clinical Practice E-Learning -> **Introduction to Good Clinical Practice eLearning (Secondary Care).** Once this e-Learning course has been completed you should receive a certificate.

Note: **GCP is only valid for 2 years after completion and must be renewed by completing a refresher course**, which is also available on the NIHR Learn website.

PI – Principal Investigator – each hospital's approved local lead for the FLO-ELA trial

SIV – Site Initiation Visit – a key part of training for each new recruiting site. For FLO-ELA this is conducted by slideset review and teleconference. These are scheduled regularly.

SOPs – Standard Operating Procedures – detailed documents with instructions for various aspects of trial conduct.

SAEs – Serious Adverse Events

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