Irish
Critical Care
Clinical Trials
Network

Principal Investigator Training Programme

ICC-PITP Programme

Guidance Document and Logbook Tool

Note: You will upload the contents of this to the online logbook at the end of your tenure to receive certification.

PLEASE DO NOT ENTER PATIENT OR SENSITIVE DATA TO THE LOGBOOK

Study Delegation Log Maintenance	*Document your activity on the study delegation log for assigned trials.* *Record your assigned roles (e.g. Sub-investigator on EPO-Trauma Trial, assigned roles: screening, consent etc) and dates you were added and signed off.*
Screening of Potential Participants	*Document your study screening activity for assigned trials during your tenure. Include how many patients and how often you screened.* *Example: Screened 2 patients for the Mega-ROX trial. Screened ICU admissions daily.*
Confirmation of Participant Eligibility	*Document your activity regarding confirming participant eligibility during your tenure.* *Example: Assessed inclusion/exclusion criteria and confirmed eligibility for 10 patients for T4P trial, averaging 2.6 patients per week during my tenure.*

Consent	*Document your consent process for each participant in the study including type of consent.* *Example: Obtained assent for 2 patients and informed consent for 1 patient in the MegaROX trial (total). This was spread out over the course of my tenure.*
Monitoring for Serious Adverse Events (SAEs) (if applicable)	*Document your monitoring process and any SAEs that occurred and include follow up actions taken (if applicable to you).* *Example: Monitored 5 patients including eligibility, and occurrence of potential permanent withholding criteria etc.* *1 patient experienced a potential SAE. Reported to PI and completed SAE form.*
Reporting of SAEs (if applicable)	*Document the occurrence of any SAEs, including how and when you reported them and actions taken (if applicable to you).* *Example: Reported 1 SAE via electronic CRF, followed up with safety officer.*
Prescription of Investigational Medicinal Product (IMP) (if applicable)	*Document your IMP prescriptions used for the study (If applicable).* *Example: IMP was prescribed for 3 patients in the REMAP-CAP trial as per protocol guidance.*
Collection and Processing of Biological Samples (if applicable)	*Document biological sample collection and processing details, including type of sample and collection and processing details.* *Example: Collected Blood samples for additional biomarker sub study. Drawn from arterial line at 12h, 24h, 48h, 72h etc. after randomisation for STEPCARE trial on 4 patients. Samples were processed as per separate sub study protocol. Reidentified, coded and labelled.*

Data Entry	*Document how, when and where you completed data entries for the study.* *Example: Entered data for 12 patients in the REDCap database for the REACT SHOCK study – 1 per month during my tenure*
Study Promotion to the Wider Department	*Describe any promotional activities you have carried out for the study, to increase engagement and awareness within the wider department.* *Example: Delivered short presentation on Mega-ROX at departmental meeting.*
Attendance at Site Investigators Meetings	*Document when and where you attended Site Investigator Meetings and any contributions you made to these meetings* *Example: Attended weekly online Site Investigator Meeting for T4P trial. Discussed approaches to consent and ways to troubleshoot local issues.*
Identification and Resolution of Recruitment Barriers	*Consider identifying potential barriers to the study in advance of recruitment. Continue to document any barriers encountered while working on the study and describe ways you overcame these barriers or could overcome them in the future.* *Example: Identified language barrier for consent in ICU; proposed multilingual leaflets; raised in PI team meeting.*
Reflections	*Note any additional thoughts.*