

POP-I Delegated Duty GCP & CV Requirements



Delegated Duty	Training required	GCP & CV required	GCP & CV to be collected by NCTU?	Other notes
Overall responsibility of trial at site	SIV	Yes	Yes	Must be PI
Initiation (training) of new trial personnel	SIV	Yes	No	
Informed consent	SIV	Yes	No	
Participant screening/ selection/ enrolment/ randomisation	SIV	Yes	No	
Medical History	SIV	Yes	No	
Confirmation of eligibility	SIV	Yes	No	Must be a medically qualified doctor
Prescribing IMP	SIV	Yes	No	
Collection of AE/SAE data	SIV	Yes	No	
Assessment of AE/SAE Criteria	SIV	Yes	No	
Reporting of SAEs in mandated timescales	SIV	Yes	No	
CRF completion/eCRF data entry	SIV	Yes	No	
eCRF / data query sign-off	SIV	Yes	No	
Data Query Completion	SIV	Yes	No	
Medical Care and supervision of participants	SIV	Yes	No	
Maintenance of Investigator Site File	SIV	Yes	No	
Filing and Archiving of Data	SIV	Yes	No	