

# Standard Operating Procedure Matrix for Research Staff Training Files (V5 - 28/07/2020)

Please check the NNUH R&D website regularly for updates on SOP's - \*\*\*please note that it is the responsibility of the post holder to ensure that all necessary SOP's (and any updated versions associated with them) have been read and understood\*\*\*

<b>This Form belongs to:</b>	<b>Please Indicate Your Post Below...</b>		
<b>Name of Line Manager:</b>	Research Nurse (RN)		
<b>NOTES:</b> SOP's noted <b>M</b> in the matrix are mandatory for the selected staff. All SOP's are available on the website <a href="http://www.nnuh.nhs.uk/research-and-innovation/information-for-researchers/standard-operating-procedures/">http://www.nnuh.nhs.uk/research-and-innovation/information-for-researchers/standard-operating-procedures/</a> Once you have read all relevant SOP's and your training has been signed off by your Line Manager, please file this form with your training records.	Healthcare Assistant (HCA) / Clinical Trial Practitioner (CTP)		
	Administrator (Adm.)		
	Research Associate/fellow/Sub Investigator/Research Facilitators/Coordinator (RA-RF-SINV-Res F-Co.)		
	Data Manager (DM) / Statistician (ST)		
	Chief or Principal Investigator (CI / PI)		

**Queries: If you have any general queries about the SOP's, please contact the NNUH R&D office.**

SOP	Title	Training by Post						I confirm that I have read and understood this SOP			I confirm that I have read and understood this <i>updated SOP</i>			I confirm that I have read and understood this <i>updated SOP</i>		
		RN	HCA / CTP	Adm.	RF-RA-Inv-Co-Re F	DM / ST	CI / PI	Version & Date	Post holder Initials & date	Line Manager's Initials & Date	Updated Version & Date	Post holder Initials & date	Line Manager's Initials & Date	Updated Version & Date	Post holder Initials & date	Line Manager's Initials & Date
SOP 001	Production, Review Approval and Control of SOPs Related to Research Activities	M	M	M	M	M	M									
SOP 002	Good Clinical Practice Training	M	M	M	M	M	M									
SOP 003	Audit Plan	M	M	M	M	M	M									
SOP 005	Grant Application				M		M									
SOP 205	Identifying, Recording and Reporting Adverse Events for Clinical Trials of Investigational Medicinal Products	M	M	M	M	M	M									
SOP 205 App 1	CTIMPS SAE Report Form															
SOP 206	Identifying, Recording and Reporting Adverse Events for Healthcare Research Studies that are not CTIMPS	M	M	M	M	M	M									
SOP 206 App 1	Non CTIMP SAE Report Form	M	M	M	M	M	M									

SOP	Title	Training by Post						I confirm that I have read and understood this SOP			I confirm that I have read and understood this updated SOP			I confirm that I have read and understood this updated SOP		
		RN	HCA / CTP	Adm.	RF-RA-Inv-Co-Re F	DM / ST	CI / PI	Version & Date	Post holder Initials & date	Line Manager's Initials & Date	Updated Version & Date	Post holder Initials & date	Line Manager's Initials & Date	Updated Version & Date	Post holder Initials & date	Line Manager's Initials & Date
SOP 207	Identifying, Recording and Reporting Adverse Events for Device Trials	M	M	M	M	M	M									
SOP 207 App 1	Device Trial SAE Report Form	M	M	M	M	M	M									
SOP 210	Breaches of Good Clinical Practice of the Trial Protocol	M	M	M	M	M	M									
SOP 210 App 1	Form for Protocol Deviation, Violation, Breach or Serious Breach of Procotol or GCP	M	M	M	M	M	M									
SOP 215	Research Study Amendments	M	M	M	M	M	M									
SOP 220	Fraud and Misconduct	M	M	M	M	M	M									
SOP 230	Urgent Safety Measures	M	M	M	M	M	M									
SOP 305	Creating and Maintaining a Trial Master File	M	M	M	M	M	M									
SOP 310	Development of Participant Information Sheet and Informed Consent Form	M	M	M	M		M									
SOP 315	Obtaining written Informed Consent from Competent Adults in Clinical Trials	M	M	M	M		M									
SOP 316	Distance (remote) Consenting for Children and Neonates in Research Studies	M	M	M	M		M									
SOP 320	Developing a Research Protocol	M	M	M	M		M									
SOP 325	Study Start up Activities for Clinical Research Trials	M	M	M	M		M									
SOP 330	Monitoring CTIMP's & Device Trials	M	M	M	M		M									
SOP 335	Site Study Closedown	M	M	M	M	M	M									
SOP 340	Clinical Trial Reporting	M	M	M	M	M	M									
SOP 345	Identifying Trial Patients on Hospital Admission	M	M	M	M		M									
SOP 350	Developing and Designing a Case Report Form (CRF)	M	M	M	M		M									

SOP	Title	Training by Post						I confirm that I have read and understood this SOP			I confirm that I have read and understood this updated SOP			I confirm that I have read and understood this updated SOP		
		RN	HCA / CTP	Adm.	RF-RA-Inv-Co-Re F	DM / ST	CI / PI	Version & Date	Post holder Initials & date	Line Manager's Initials & Date	Updated Version & Date	Post holder Initials & date	Line Manager's Initials & Date	Updated Version & Date	Post holder Initials & date	Line Manager's Initials & Date
SOP 351	Completing a Case Report Form (CRF)	M	M	M	M		M									
SOP 355	Establishing Identity of Participants in Research	M	M	M	M		M									
SOP 400	Joint Arrangements for Research Authorisation of Research Sponsorship	M	M	M	M		M									
SOP 405	Obtaining and maintaining Medicines and Healthcare products Regulatory Agency (MHRA) approval for a Clinical Trial	M	M	M	M		M									
SOP 410	Set up and Initiation of an Investigator Site	M	M	M	M		M									
SOP 505	Creating and Maintaining Training Records	M	M	M	M	M	M									
SOP 510	Medical Cover for Clinical Research Trials	M	M	M	M	M	M									
SOP 600	Creating a Statistical Analysis Plan				M	M	M									
SOP 605	Sample Size Calculation				M	M	M									
SOP 700	Vendor Selection & Oversight	M			M		M									
SOP 705	Quality Control and Quality Assurance	M	M	M	M	M	M									
SOP 710	Audit and Inspection	M	M	M	M		M									
SOP 715	Principles of Clinical Research Laboratory Practice	M	M	M	M		M									
SOP 720	Risk assessment of Trials sponsored by the NNUH/UEA	M	M	M	M		M									
SOP 725	Capacity, Capability and Risk Assessment at NNUH of Hosted Studies.	M	M	M	M		M									
SOP 730	Computer System Validation	M	M	M	M	M	M									
SOP 800	Non Study Specific Document Management	M	M	M	M	M	M									

SOP	Title	Training by Post						I confirm that I have read and understood this SOP			I confirm that I have read and understood this updated SOP			I confirm that I have read and understood this updated SOP		
		RN	HCA / CTP	Adm.	RF-RA-Inv-Co-Re F	DM / ST	CI / PI	Version & Date	Post holder Initials & date	Line Manager's Initials & Date	Updated Version & Date	Post holder Initials & date	Line Manager's Initials & Date	Updated Version & Date	Post holder Initials & date	Line Manager's Initials & Date
SOP 805	Trial Data Management System (TDMS): Project Set up	M	M	M	M	M	M									
SOP 810	TDMS: Specification, Development, Test and Deployment	M	M	M	M	M	M									
SOP 815	TDMS: Lock, Freeze and Unfreeze of Databases	M	M	M	M	M	M									
SOP 820	TDMS: Maintenance and Support	M	M	M	M	M	M									
SOP 825	TDMS: Validation	M	M	M	M	M	M									
SOP 835	TDMS: Emergency Unblinding	M	M	M	M	M	M									
SOP 840	TDMS: Data Management and Security	M	M	M	M	M	M									
SOP 850	TDMS: Closedown	M	M	M	M	M	M									
SOP 855	TDMS: Manipulation of Data after Export	M	M	M	M	M	M									
SOP 860	TDMS: Data Request	M	M	M	M	M	M									
SOP 865	Study Specific Document Management	M	M	M	M	M	M									
SOP 900	Storage and Retention of Research Documents	M	M	M	M	M	M									
SOP 900 App1	Delivery Team Archiving Process Map	M	M	M	M	M	M									
SOP 900 App2	Delivery Team Archiving Checklist	M	M	M	M	M	M									
SOP 900 App 3	Archiving Inventory	M	M	M	M	M	M									
SOP 900 App 4	Chain of Custody Form	M	M	M	M	M	M									
SOP 900 App 5	Archive Facility Email Template	M	M	M	M	M	M									
SOP 900 App 6	Request for Archiving Retrieval	M	M	M	M	M	M									
SOP 900 App 7	Destruction Certificate	M	M	M	M	M	M									

SOP	Title	Training by Post						I confirm that I have read and understood this SOP			I confirm that I have read and understood this <i>updated SOP</i>			I confirm that I have read and understood this <i>updated SOP</i>			
		RN	HCA / CTP	Adm.	RF-RA-Inv-Co-Re F	DM / ST	CI / PI	Version & Date	Post holder Initials & date	Line Manager's Initials & Date	Updated Version & Date	Post holder Initials & date	Line Manager's Initials & Date	Updated Version & Date	Post holder Initials & date	Line Manager's Initials & Date	
SOP 900 App 8	R&D Archiving Process Map			M	M												
SOP 900 App 9	R&D Archiving Check list			M	M												
2.9c_1	<b>PHARMACY SERVICES: Procedure for the Labelling Requirements of Investigational Medicinal Products</b>	This SOP is mandatory for all staff involved in CTIMP															
2.9e_1	<b>PHARMACY SERVICES: Procedure for Clinical Trial Services at the Clinical Research and Trials Unit at the University of East Anglia</b>	This SOP is mandatory for all staff at the CRTU and Pharmacy, involved in CTIMP where the IMP is delivered to the Pharmacy holding room or directly to the patient at the CRTU-UEA base.															
2.9e_2	<b>PHARMACY SERVICES: Standard Operating Procedure for the Transfer of Investigational Medicinal Products between NNUH Trust sites</b>	This SOP is mandatory for all staff at the CRTU and Pharmacy, involved in CTIMP where the IMP is delivered at the CRTU-UEA base.															
2.9b_14	<b>PHARMACY SERVICES: Standard Operating Procedure for the Management of Investigational Medicinal Products outside Pharmacy</b>	This SOP is mandatory for all staff at the CRTU and Pharmacy, involved in CTIMP where the IMP is stored outside Pharmacy															