Standard Operating Procedure Matrix for Research Staff Training Files
SOP 505a Trust Docs ID 14992 (V10)

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

This Form belongs to:		**Please Indicate Your Post Below…**	
Name of Line Manager:		**Research Nurse (RN)**	
NOTES: SOPs noted **M** in the matrix are mandatory for the selected staff. All SOPs are available on the website http://www.nnuh.nhs.uk/research-and-innovation/information-for-researchers/standard-operating-procedures/ Once you have read all relevant SOPs 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/Co-ordinator (RA-RF-SINV-Res F-Co.)	
		Data Manager (DM) / Statistician (ST)	
		Chief or Prinicipal Investigator (CI / PI)	

Queries: If you have any general queries about the SOPs, 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 *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 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 004	Research Passports and NNUH Access			**M**			**M**									
SOP 005	Grant Application				**M**		**M**									
SOP 205	Identifiying, 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	**M**	**M**	**M**	**M**	**M**	**M**									

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SOP 206	Identifiying, 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 207	Identifiying, 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**									
SOP317	Obtaining Consent Remotely for adults	**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**									

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SOP 330	Monitoring CTIMP's & Device Trials	**M**	**M**	**M**	**M**		**M**									
SOP 331	Remote Monitoring of Clinical 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 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 401	Sponsorship Request and Approval for Research Studies and Clinical Trials	**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 410 App 1	Site Initiation Check List	**M**	**M**	**M**	**M**		**M**									
SOP 410 App 2	Site Initiation Agenda Template	**M**	**M**	**M**	**M**		**M**									
SOP 505	Creating and Maintaining Training Records	**M**	**M**	**M**	**M**	**M**	**M**									
SOP 505a	SOP Matrix for Research Staff Training Records	**M**	**M**	**M**	**M**	**M**	**M**									
SOP 510	Medical Cover for Clinical Research Trials	**M**	**M**	**M**	**M**	**M**	**M**									

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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 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 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									

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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 6	Request for Archiving Retrieval	**M**	**M**	**M**	**M**	**M**	**M**									
SOP 900 App 8	R&D Archiving Process Map			**M**	**M**											
2.9c_1	***PHARMACY SERVICES: Procedure for the Labelling Requirements of Investigational Medicinal Products***	**This SOP is mandatory** for all staff involved in CTIMP														
2.9b_14	***PHARMACY SERVICES: Standard Operating Procedure for the Management of Investigational Medicinal Products outside Pharmacy***	**This SOP is mandatory for all staff at the CRF and Pharmacy, involved in CTIMP where the IMP is stored outside Pharmacy**														
2.9e_3	***PHARMACY SERVICES: Standard Operating Procedure for Investigation Medicinal Product Management in the CRF at the Quadram Institute***	**This SOP is mandatory for all staff at the CRF and Pharmacy, involved in CTIMP where the IMP is stored outside Pharmacy**														