NIHR Guideline B01 R&D Operational Capability Statement

Version History

Version number Valid from Valid to Date approved Approved by Updated by 12/12/2012 12/12/2013 RDOCS 001 **R&D Steering Group** Laurie Wrench RDOCS 002 (R&D-SOP-019) 01/06/2014 31/05/2015 18/07/2014 CEG Louise Alston

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Introduction to North Staffordshire Combined Healthcare NHS Trust

North Staffordshire Combined Healthcare NHS Trust (NSCHT) headquaters are located on the borders of Stoke-on-Trent and Newcastle-under-Lyme. NSCHT is the main provider of mental health services of approximately half-a-million people living in and around North Staffordshire. The Trust has a turnover of approximately £86 million per year, with a workforce circa 1,500 (1300 WTE) (2013/2014). NSCHT provide a range of mental health, specialist learning disability and related services for people of all ages including: adult mental health and social care; children and young people services; learning disability services; neuropsychiatry services and older people's services. The Trust's purpose is working to improve the mental health and well-being of local communities.

Population served: 463,000

Geographical area: The city of Stoke-on-Trent and North Staffordshire county cover both urban and rural areas

Organisation R&D Management Arrangements

Information on key contacts

Organisation Details	
Name of Organisation	North Staffordshire Combined Healthcare NHS Trust
R&D Lead / Director (with responsibility for reporting on R&D to	Dr Richard Hodgson, R&D Director
the Organisation Board)	
R&D Office details:	
Name:	NSCHT R&D Department
Contact Number:	01782 441 687
Contact Email:	<u>r&d@northstaffs.nhs.uk</u>
Key Contact Details e.g. Research Governance Lead, NHS Permissi	ons Signatory contact details
Contact 1:	
Role:	Head of Clinical Audit and R&D
Name:	Laurie Wrench
Contact Number:	01782 441 651
Contact Email:	laurie.wrench@northstaffs.nhs.uk
Contact 2:	
Role:	R&D Director
Name:	Dr Richard Hodgson
Contact Number:	0300 7900 237
Contact Email:	richardE.hodgson@northstaffs.nhs.uk
Contact 3:	

Role:	Research Governance Facilitator
Name:	Louise Alston
Contact Number:	01782 441 687
Contact Email:	louise.alston@northstaffs.nhs.uk
Contact 4:	
Role:	Clinical Studies Officer
Name:	Kerri Bailey
Contact Number:	01782 441774
Contact Email:	kerri.bailey@northstaffs.nhs.uk
Contact 5:	
Role:	Research Nurse (Lead)
Name:	Sue Wood
Contact Number:	01782 441773
Contact Email:	sueP.wood@northstaffs.nhs.uk

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Information on staffing of the R&D Office

R&D Office Roles (e.g. Governance, Contracts, etc)	Whole Time Equivalent	Commments indicate if part time/full time/shared/joint etc
Head of Clinical Audit and R&D	1	Full time
Research Governance Facilitator	0.6	3 days a week
Clinical Studies Officer	1	Full time
Research Nurse	0.6	3 days a week
Research Associate	0.2	1 day a week
Director of R&D	I PA	4 hours a week
Clinical Effectiveness Support Officer	0.3	1.5 days a week

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Information on reporting structure in organisation (include information on any relevant committees, for example, a Clinical Research Board / Research Committee / Steering Committee.) **Reporting Structures NSCHT Clinical Audit and Research & Development Office Organisation Chart** MEDICAL DIRECTOR DIRECTORATE REPRESENTATIVES Adult Mental Health Inpatient Adult Mental Health Community Research and Substance Misuse Research Associate **Development Director** Neuro & Old Age Psychiatry Learning Disability Children & Adolescent Mental Health Head of Clinical Audit & `L_____ Research and Development Deputy Clinical Audit Research Nurse Study Monitor Clinical Studies Officer Manager (0.6 wte) (vacant) **Grant Writing** Research Governance Support Officer **Clinical Auditor** Clinical Auditor Facilitator (0.6 wte) (0.2 wte)

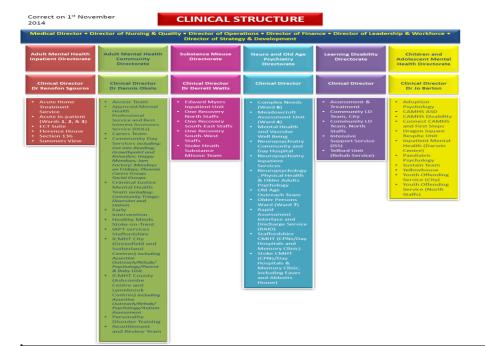
Direct Line Management Responsibility

Clinical Effectiveness

Support Officer (0.6 wte)

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Organisational Structure



lumber and types of teams in each speciality				
Directorate	Service	Number of teams/wards		
Children & Adolescent Mental Health	CAMHS and First Steps	4 teams		
	ASD	2 teams		
	Disability Service	1 team		
	Paediatric Psychology	1 team		
	Youth Offending Service	2 teams		
	Inpatient	1 team		
Learning Disability	Inpatient	2 teams		
	Outpatient/Community	3 teams		
Adult Mental Health Community	Day Services	8 teams		
	ICMHTs	12 teams		
	Access Team	1 team		
	DOLs	2 teams		
	Carers team	1 team		
	Criminal Justice Mental Health	3 teams		
	Early Intervention	2 teams		
	IAPT	2 teams		
	Personality Disorder	1 team		
	Rehabilitation and Continuing Care	6 teams		
Adult Mental Health Inpatient	Acute Home Treatment	1 team		
	Acute Inpatient	3 teams		

	Community Inpatient	2 teams
	ECT service	1 team
Substance Misuse	Inpatient	1 team
	One Recovery	3 teams
	Prison Outreach	1 team
Neuro and Old Age Psychiatry	Inpatient (Neuro)	1 team
	Inpatient (Older People)	1 team
	Outpatient / Community (Neuro)	4 teams
	Outpatient / Community (Older People)	9 teams
	RAID	1 team

Information on Research Networks supporting/working with the Organisation.

Information on how the Organisation works with the Local Clinical Research Network (LCRN), and specialties within the network

Research Networks	
Research Network (name/location)	Role/relationship of the Research Network eg host Organisation
West Midlands Local Clinical Research Network	Partner
Mental Health Specialty	Partner
Dementia & Neurodegenerative Diseases Specialty	Partner
Medicines for Children Specialty	Partner
Non Medicines for Children Specialty	Partner
Primary Care Specialty	Partner
Stroke Specialty	Partner
West Midlands Academic Health Science Network	Liaison when suitable studies are identified

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Information on collaborations and partnerships for research activity (e.g. BRC, BRU, Other NHS Organisations, Higher Education Institutes, Industry)

Current Collaborations / Partnerships			
Organisation Name	Details of Collaboration / Partnership (eg University/Organisation Joint Office, external provider of pathology services to Organisation, etc, effective dates)	Contact Name	Contact Email
Staffordshire University	Trust is collaborator in research with Staffordshire University (student research)	Professor Helen Dent	helen.dent@staffs.ac.uk
Keele University	Trust is collaborator in research with Keele University (student research and dementia research)	Nicola Leighton	n.leighton@keele.ac.uk
University of Birmingham	Birmingham Clinical Trials Unit provides the Trust with support on data entry, storage and analysis (Stroke SOS clinical trial)		bctu@contacts.bham.ac.uk
University of Manchester	Trust is collaborator in research with Manchester University (Suicide/Homicide research)	Dr Sharon McDonnell	sharonJ.mcdonnell@manchester.ac.uk
University of Southampton	Trust is collaborator in research with University of Southampton (CAMHS)	Dr Donna McCann	d.c.mccann@soton.ac.uk

University of Nottingham	Trust is collaborator in research with University of Nottingham (CAMHS)	Professor David Daley	david.daley@nottingham.ac.uk
South Staffordshire & Shropshire NHSFT	Trust is collaborator in research with SSSFT and Collaborative working with research governance	Dr Ruth Lambley-Burke	ruth.lambley-burke@sssft.nhs.uk
	UHNS provides support services (Pathology, Radiology, Surgery) in relation to research	Dr Darren Clement	darren.clement@northstaffs.nhs.uk
Birmingham & Solihull Mental Health NHSFT	Trust is collaborator in research with BSMHT (Huntington's Disease research)	Dr Hugh Rickards	hugh.rickards@bsmht.nhs.uk
West Midlands Ambulance Service NHST	Trust is collaborator in research with WMAS (suicide bereavement)	Ms Gill Price	gill.price@wmas.nhs.uk
Stoke on Trent City Council	Trust is collaborator in research with SOT Local Authority (dementia research)	Mr Peter Ball	peter.ball@stoke.gov.uk
Stoke on Trent CCG	Partner in North Staffordshire wide Research Strategy	Dr Ruth Chambers	ruth.chambers@stoke.nhs.uk
North Staffordshire CCG	Partner in North Staffordshire wide Research Strategy	Dr Julie Oxtoby	julie.oxtoby@uhns.nhs.uk
NIHR Research Design Service (West Midlands)	RDS help the Trust's researchers develop ideas into NIHR funding bids	Roger Beech	<u>r.beech@cphc.keele.ac.uk</u>
Formerly North Staffordshire Primary Care Trust	Trust is collaborator in research with NSPCT (PIC sites)	Dr Mark Stone	mark.stone@northstaffs.nhs.uk
Quintiles	Trust is a preferred site with the Contract Research Organisation (CRO)		
The Royal Wolverhampton NHSFT	RWH host the WM CRN	Dr Sarah Glover	sarah.glover@nhs.net

Organisation Study Capabilities

Information on the types of studies that can be supported by the Organisation to the relevant regulatory standards

Types of Studies Organisation has capabilities in (please tick appl	licable)					
	CTIMPs (indicate Phases)	Clinical Trial of a Medical Device	Other Clinical Studies	Human Tissue: Tissue Samples Studies	Study Administering Questionnaires	Qualitative Study
A-CiOiti	(illulcate Filases)	ivieuicai Device		Samples Studies	Questionnaires	
As Sponsoring Organisation	Х	Х	٧	٧	٧	√
As Participating Organisation	Phase II-IV	٧	٧	٧	٧	٧
As Participant Identification Centre	Phase II-IV	٧	٧	٧	٧	V

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Organisation Services

Information on key clinical services contacts and facilities/equipment which may be used in studies for suporting R&D governance decisions across the organisation.

Clinical Service Departments				
Service Department	Specialist facilities that may be provided (eg number/type of scanners)	Contact Name	Contact Email	Contact Number
Pharmacy	The Trust has an on-site Pharmacy Clinical Trials Service, with a dedicated Clinical Trials Pharmacist (0.5 WTE) and Clinical Trials Pharmacy Technician (0.5 WTE). There are SOPs in place for the clinical trials that take place. There are secure storage facilities (alarms, digital/manual lock), remote temperature monitor of fridges (sends text message to on-call pharmacist in the event of a power failure/temperature deviation), on-call out-of-hours service (code breaks/advice), and all permanent staff are GCP trained.		chik.tan@northstaffs.nhs.uk	01782 441604
Pathology	The Trust, as a specialist mental health service, does not have an in-house laboratory facility, however it has an SLA with the neighbouring acute Trust (University Hospital of North Staffordshire NHS Trust (UHNS)) for pathology services. The Pathology Laboratory at UHNS offers a comprehensive range of routine and specialist investigations to the population of North Staffordshire as well as a tertiary service covering both Cheshire and Shropshire. It offers extended core hours and a 24/7 out-of-hours service. It is active in research, both in supporting clinical trials and in chief-investigator-led primary research.		elizabeth.williamson@uhns.nhs.uk	01782 674253

Radiology / Imaging	The Trust, as a specialist mental health service,	Kay Jones / Bruce Jarvest	kay.jones@uhns.nhs.uk	01782 675883 / 675873
	does not have an in-house imaging facility,		bruce.jarvest@uhns.nhs.uk	
	however it has an SLA with the neighbouring acute			
	Trust (University Hospital of North Staffordshire			
	NHS Trust (UHNS)) for radiology services. The			
	Radiology and Imaging Departments at UHNS are			
	integral to clinical trials taking place. There is a			
	dedicated research group led by the Lead			
	Radiographer which supports feasibility, set-up			
	and conduct of clinical trials involving			
	imaging/radiology services. The equipment used			
	are three high specification MRI scanners, two 3			
	Tesla and one 1.5 Tesla. UHNS have also just			
	purchased a PET/CT scanner. The MRI scanners			
	are Wide Bore and able to take patients up to			
	250kg in weight. The scanners also have			
	removable "docking tables" to allow a patient to			
	be managed outside the scan room, and, for			
	patients who require "settling down" beforehand			
	the additional "docking table" which attaches to			
	the MRI scanner, can be used outside the room to			
	allow the patient to acclimatise to the			
	environment whilst the scanner is in use. For the			
	claustrophobic patients there is a short length,			
	wide bore machine.			

Key Signatories for Research Governance (two per department so that cover is always available)

Details of Sign Off	Name and Designation	Department	Contact Email	Contact Number
Final R&D sign-off	Dr Richard Hodgson, R&D Director	Research &	richardE.hodgson@northstaffs.nhs.uk	0300 7900 237
		Development		
Final R&D sign-off	Dr Buki Adeyemo, Medical Director	Research &	olubukola.adeyemo2@northstaffs.nhs.uk	01782 441619
		Development		
Clinical Trial Agreement Authorisation	Dr Richard Hodgson, R&D Director	Research &	richardE.hodgson@northstaffs.nhs.uk	0300 7900 237
		Development		
Clinical Trial Agreement Authorisation	Dr Buki Adeyemo, Medical Director	Research &	olubukola.adeyemo2@northstaffs.nhs.uk	01782 441619
		Development		
Public Relations Risk	Annie Roberts, Head of Communications	Communications	annie.roberts@northstaffs.nhs.uk	0300 123 1535
Public Relations Risk	Penny Gibbs, Communications Officer	Communications	penny.gibbs@northstaffs.nhs.uk	0300 123 1535
Caldicott Guardian/Data Protection Issues	Dr Buki Adeyemo, Medical Director	Research &	olubukola.adeyemo2@northstaffs.nhs.uk	01782 441619
		Development		
Caldicott Guardian/Data Protection Issues	Mr Glen Sargeant, Head of Performance & IT	Information Governance	glen.sargeant@northstaffs.nhs.uk	01782 275125
Clinical Director sign-off - Adult Mental Health Community	Dr Dennis Okolo, Clinical Director	АМНС	dennis.okolo@northstaffs.nhs.uk	0300 7900 237
Clinical Director sign-off - Adult Mental Health Inpatient	Dr Xenofon Sgouros, Clinical Director	АМНІ	xenofon.sgouros@northstaffs.nhs.uk	01782 441600
Clinical Director sign-off - Children & Young People	Dr Jo Barton, Clinical Director	СҮР	joanne.barton@northstaffs.nhs.uk	01782 408350
Clinical Director sign-off - Substance Misuse	Dr Derrett Watts, Clinical Director	SM	derrettJ.watts@northstaffs.nhs.uk	01782 441600
Clinical Director sign-off - Learning Disability	Vacant	LD		

Clinical Director sign-off - Neuro & Old Age Psychiatry	Vacant	NOAP		
Clinical Support Service - Pharmacy sign-off	Chik Tan, Clinical Trials Pharmacist / Principal Pharmacist	Pharmacy	chik.tan@northstaffs.nhs.uk	01782 441604
Clinical Support Service - Pharmacy sign-off	Louise Jackson, Chief Pharmacist	Pharmacy	louise.jackson@northstaffs.nhs.uk	01782 275158

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Information on key management contacts for suporting R&D governance decisions across the organisation.

Management Support e.g. Finance, Legal Service Department		Contact Name	Contact Email	Contact Number
Archiving	Named Archivist is responsible for all research archiving within the Trust. The process is governed by a SOP. Off site arrangements are also managed by the R&D Office.	Louise Alston	louise.alston@northstaffs.nhs.uk	01782 441687
Contracts	All research contracts are negotiated by the R&D Manager, and authorised by the R&D Director. Use of model agreements are encouraged wherever possible.	Laurie Wrench	laurie.wrench@northstaffs.nhs.uk	01782 441651
Data Management support	The Information Technology (IT) Department can provide guidance on data management for research trials in collaboration with the R&D Office.	Glen Sargeant	glen.sargeant@northstaffs.nhs.uk	01782 275125
Finance	The Trust has a dedicated finance lead for research who is responsible for the finance side of research within the Trust.	Dawn Richardson	dawn.richardson@northstaffs.nhs.uk	01782 275062
Information Technology	IT queries specific to research can be directed to the IT Services Manager. If the IT Services Manager requires research guidance he will contact the R&D Office.	Glen Sargeant	glen.sargeant@northstaffs.nhs.uk	01782 275125
Legal	Access to legal services is through the R&D Office.	Laurie Wrench	laurie.wrench@northstaffs.nhs.uk	01782 441651
Statistical support	Access to statistical support is through the R&D Office.	Laurie Wrench	laurie.wrench@northstaffs.nhs.uk	01782 441651
Human Resources/personnel	The Research Governance Facilitator is responsible for the HR side of research within the Trust (i.e. checking researchers are appropriately trained, qualified, experienced and dealing with HRC/LOA/RP considerations). HR will be consulted in any DBS clearance issues.	Alexa Lloyd	louise.alston@northstaffs.nhs.uk alexa.lloyd@northstaffs.nhs.uk	01782 441687 01782 441685

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Organisation R&D Interests

Information on the areas of research interest to the Organisation

Organisation R&D Areas of Interest			
Area of Interest	Details	Contact Name	Contact Email
	Anxiety/Depression, Bipolar Disorder, Personality	Dr Richard Hodgson, Dr Ravindra Belgamwar, Dr Darren Carr, Dr Derrett Watts, Dr Sasalu Shivamurthy	richardE.hodgson@northstaffs.nhs.uk
Learning Disabilities	, , , , , ,	Dr Marian Seager, Dr Pernia Arshad, Dr Sridhar Sridharan	marian.seager@northstaffs.nhs.uk

Children & Young People	Attention Deficit Hyperactivity Disorder (ADHD),	Dr Jo Barton	joanne.barton@northstaffs.nhs.uk
	Eating Disorders		
Neuropsychiatry	Huntington's Disease, Brain Injury	Dr George El-Nimr	georgeNI.el-nimr@northstaffs.nhs.uk
Older Adults Mental Health	Dementia, Parkinsons	Dr Ben Udeze, Dr Sridhar Sridharan	bernard.udeze@northstaffs.nhs.uk
Clinical Psychology		Dr Jennie Lonsdale, Dr Laura Stokes	jennifer.lonsdale@northstaffs.nhs.uk

Information on Local / National Specialty group membership within the Organisation which has been shared with the CLRN

Specialty Group Membership (Local and National)				
National / Local	Specialty Group	Contact Name	Contact Email	
Local	Mental Health	Dr Richard Hodgson	richardE.hodgson@northstaffs.nhs.uk	
Local/regional	Dementias & Neurodegenerative Diseases	Dr George El-Nimr	georgeNI.el-nimr@northstaffs.nhs.uk	
Local/regional	Stroke	Professor Christine Roffe	christine.roffe@uhns.nhs.uk	

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Organisation R&D Planning and Investments

Planned Investment		
Area of Investment (e.g. Facilities, Training, Recruitment, Equipment etc.)	Description of Planned Investment	Status of Planned Investment
GCP Training	Provision of GCP training for all researchers in the Trust via WM CRN	Ongoing
PANSS Training	Delivery of in-house training programme	Ongoing
GCP Facilitator	Facilitator training for Research Nurse to enable facilitation of in-house training programme	Ongoing
Research Associate Apprenticeships	Investment in resource and funding for RA Apprenticeships within R&D Department for potential researchers within the Trust	Ongoing
Good Pathology Practice Training	Investment in local training for CSO + RN to be trained in simple pathology procedures	Ongoing

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Organisation R&D Standard Operating Procedures Register

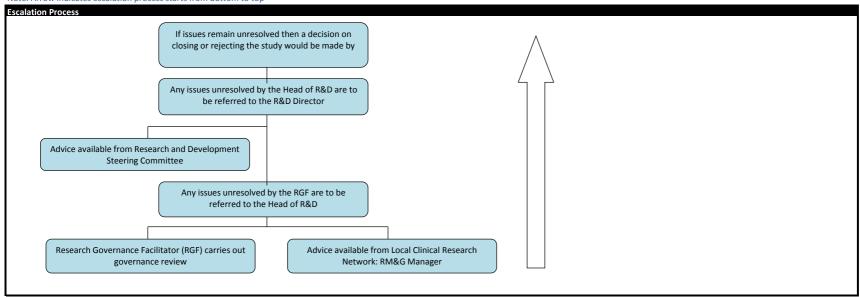
Standard Operating Procedures			
SOP Ref Number	SOP Title	SOP Details	
R&D-SOP-001	Preparation, Review and Approval of Standard Operating Procedures for Research	v1.1	
R&D-SOP-002	Monitoring Income and Expenditure for R&D	v1.1	
R&D-SOP-003	Roles and Responsibilities of Divisional Representatives on the Research and Development Steering Group	v1.1	
R&D-SOP-004	Minimum Training Requirements for Researchers at NSCHT	v1.1	
R&D-SOP-005	Notification of Serious Breach of GCP or the Trial Protocol	v1.0	
R&D-SOP-006	Research Related Adverse Event Reporting Procedure	v1.0	
R&D-SOP-007	Safety Reporting	v1.0	
R&D-SOP-008	R&D SAE and SUSAR Handling Procedure	v1.0	
R&D-SOP-009	Ensuring Study Oversight	v1.0	
R&D-SOP-010	Amendments	v1.0	
R&D-SOP-011	Delegation of Roles and Resposbilities for NSCHT Sponsored Research Studies	v1.0	

		1
R&D-SOP-012	Monitoring of CTIMPS at NSCHT	v1.0
R&D-SOP-013	Archiving	v1.0
R&D-SOP-014	Trial Close-out	v1.0
R&D-SOP-015	Set-up and Management of Research Studies at NSCHT	v1.0
R&D-SOP-016	Application to NSCHT for Sponsorship of a Research Study	v1.0
R&D-SOP-017	Informed Consent	v1.0
R&D-SOP-018	Receiving and Acknowledging Safety Notifications to R&D	v1.0
R&D-SOP-019	R&D Operational Capability Statement	v1.1
R&D-SOP-020	Granting NHS Permission	v1.0
R&D-SOP-021	Application Process for an HRC, LOA or RP	v1.0
R&D-SOP-022	Managing MHRA Inspections	v1.0
R&D-SOP-023	R&D Processing of Amendments	v1.0
R&D-SOP-024	R&D Approval Process for PICs	v1.0

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Information on the agreed Escalation Process to be used when R&D governance issues cannot be resolved through normal processes. Note: Arrow indicates escalation process starts from bottom to top



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Other Information

For example, where can information be found about the publications and other outcomes of research which key staff led or callaborated in?

Other Information (relevant to the capability of the Organisation)

Information about research activity within the Trust can be found in staff publications in scientific journals, staff intranet, R&D section on staff intranet, R&D activity and performance report on Trust website, poster/notice

boards within Trust HQ, poster presentations at internal and external events, Hospital and community services, Trust and R&D Department Newsletters, Trust CA/CE Annual Report, R&D Steering Group minutes, NIHR website, Internal Interested Researcher's electronic mailing list, Clinical Research Network (CRN) events.

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