

# North Bristol NHS Trust

## NIHR R&D Operational Capability Statement

### Version History

Version number	Valid from	Valid to	Date approved	Approved by	Updated by
RDOCS 001	01/01/2011	31/01/2012	14/01/2011	Research Committee	Helen Lewis
RDOCS 002	01/04/2016	31/03/2017	15/09/2016	R&I Senior Team	Helen Lewis-White
RDOCS 003	01/04/2017	31/03/2018	31/05/2017	R&I Senior Team	Helen Lewis-White

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### Organisation R&D Management Arrangements

Information on key contacts

Organisation Details	
Name of Organisation	North Bristol NHS Trust
R&D Lead / Director (with responsibility for reporting on R&D to the Organisation Board)	Chris Burton (Medical Director) - Executive Director with Board level responsibility David Wynick (Director of Research) Rebecca Smith (Deputy Director of Research)
<b>R&amp;D Office details:</b>	
Name:	Research and Innovation
Address:	3rd Floor, Learning and Research Building, Southmead Hospital, Westbury-on-Trym, Bristol, BS10 5NB
Contact Number:	Tel: 0117 414 9330 Fax: 0117 414 9329
Contact Email:	<a href="mailto:research@nbt.nhs.uk">research@nbt.nhs.uk</a>
Other relevant information:	<a href="http://www.nbt.nhs.uk/research">www.nbt.nhs.uk/research</a>
<b>Key Contact Details</b> e.g. Research Governance Lead, NHS Permissions Signatory contact details	
<b>Contact 1:</b>	
Role:	Confirmation of capability and capacity; Contracts signatory
Name:	Rebecca Smith (Deputy Director of Research)
Contact Number:	0117 414 9332
Contact Email:	<a href="mailto:rebecca.smith30@nhs.net">rebecca.smith30@nhs.net</a>
<b>Contact 2:</b>	
Role:	Research operations lead
Name:	Helen Lewis-White (Research Operations Manager)
Contact Number:	0117 414 9333
Contact Email:	<a href="mailto:helen.lewis-white@nbt.nhs.uk">helen.lewis-white@nbt.nhs.uk</a>
<b>Contact 3:</b>	
Role:	Human resource management for research
Name:	Angelo Micciche (Research Infrastructure Manager)
Contact Number:	0117 414 9334
Contact Email:	<a href="mailto:angelo.micciche@nbt.nhs.uk">angelo.micciche@nbt.nhs.uk</a>
<b>Contact 4:</b>	
Role:	Management of research nurses, midwives and allied health professionals
Name:	Deborah Warbrick (NBT Research Matron)
Contact Number:	0117 414 9331
Contact Email:	<a href="mailto:deborah.warbrick@nbt.nhs.uk">deborah.warbrick@nbt.nhs.uk</a>
<b>Contact 5:</b>	
Role:	Development and management of research grants
Name:	Rebecca Coad (Research Development Manager)
Contact Number:	0117 414 9341
Contact Email:	<a href="mailto:rebecca.coad@nbt.nhs.uk">rebecca.coad@nbt.nhs.uk</a>
<b>Contact 6:</b>	

Role:	Financial performance of research projects and grants
Name:	James Fuerstenberg (Finance Business Partner - Facilities & Corporate Directorates)

Contact Number:	0117 414 3801
Contact Email:	<a href="mailto:James.Fuerstenberg@nbt.nhs.uk">James.Fuerstenberg@nbt.nhs.uk</a>

Information on staffing of the R&D Office

R&D Team		
R&D Office Roles (e.g. Governance, Contracts, etc)	Whole Time Equivalent	Comments indicate if shared/joint/week days in office etc
Director	0.25	Joint post with University Hospitals Bristol NHS Foundation Trust
Deputy Director	1	
Research Operations Manager	1	
NBT Research Matron	1	
Research Infrastructure Manager	1	
Research Development Manager	0.7	
Clinical Trials Manager	1	Clinical Trials Manager is currently on maternity leave
Clinical Trials Officer	1.6	1.0 WTE Clinical Trials Officer is covering maternity leave of Clinical Trials Manager
Research Facilitator	2.8	
Contracts & Quality Management Officer	1	
Research Development Officer	1	
Communications & PPI Manager	1	
Research Infrastructure Assistant	1	
Research Facilitation Administrator	1	
Research Development Administrator	1	
PA & R&I Administrator	1	

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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
R&I has a senior management team that meet on a monthly basis. Members of <b>R&amp;I Senior Team</b> are: Deputy Director of Research; Research Operations Manager; Research Infrastructure Manager; NBT Research Matron; Research Development Manager and Finance Business Partner; R&I Senior Team reports to the <b>Research &amp; Innovation Group (RIG)</b> on a quarterly basis. The RIG is chaired by the Trust's Medical Director. R&I Senior Team provide a research performance report for Trust Management Team and Trust Board via the RIG.

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Information on Research Networks supporting/working with the Organisation.

Information on how the Organisation works with the Comprehensive Local Research Network (CLRN).

Research Networks	
Research Network (name/location)	Role/relationship of the Research Network eg host Organisation
NIHR Clinical Research Network: West of England	This network encompasses all clinical specialities and provides funding to support the infrastructure and management of NIHR adopted clinical trials.

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Information on collaborations and partnerships for research activity (e.g. Biomedical Research Centre/Unit, Other NHS Organisations, Higher Education Institutes, Industry)

Current Collaborations / Partnerships			
Organisation Name	Details of Collaboration / Partnership (eg	Contact Name	Email address
University Hospitals Bristol NHS Foundation Trust	Joint Director of R&I with North Bristol NHS Trust	Diana Benton (Deputy Director of Research)	<a href="mailto:diana.benton@uhbristol.nhs.uk">diana.benton@uhbristol.nhs.uk</a>
University of Bristol	Appointment of clinical academics	Professor Tim Peters (School of Clinical Sciences, Head of School)	<a href="mailto:tim.peters@bristol.ac.uk">tim.peters@bristol.ac.uk</a>
		Amanda Carmichael (School of Clinical Sciences, School Manager)	<a href="mailto:amanda.carmichael@bristol.ac.uk">amanda.carmichael@bristol.ac.uk</a>
University of the West of England, Bristol	Appointment of clinical academics	Professor Jenny Ames (Associate Dean (Research, Innovation and Partnerships))	<a href="mailto:jenny.ames@uwe.ac.uk">jenny.ames@uwe.ac.uk</a>
	Provision of statistical services	Dr Paul White (Associate Professor, Applied Statistics)	<a href="mailto:paul.white@uwe.ac.uk">paul.white@uwe.ac.uk</a>
Bristol Health Partners	A Bristol wide strategic health research and innovation partnership between NHS and academia and the local authority dedicated to fostering excellence in infrastructure and people to realise the full potential of research and innovation to benefit health		<a href="mailto:hello@bristolhealthpartners.org.uk">hello@bristolhealthpartners.org.uk</a> ; <a href="http://www.bristolhealthpartners.org.uk">www.bristolhealthpartners.org.uk</a>

NIHR Research Design Service - South West (RDS-SW)	The Research Design Service in the South West is part of the NIHR infrastructure and exists to provide advice and support for people preparing NIHR grant applications	Dr Jenny Ingram (Research Consultant RDS-SW Bristol Office)	<a href="mailto:jenny.ingram@bristol.ac.uk">jenny.ingram@bristol.ac.uk</a>
West of England Academic Health Science Network (WEAHSN)	Network of NHS, universities, industry, NHS commissioners and others working together to put innovation at the heart of healthcare, to improve patient outcomes and contribute to wealth creation	Dr Elizabeth Dymond (Deputy Director of Enterprise and Translation)	<a href="mailto:elizabeth.dymond@weahsn.net">elizabeth.dymond@weahsn.net</a>
Collaboration for Leadership in Applied Health Research and Care (CLAHRC West)	Collaborative partnership between NHS, NHS commissioners, universities, local authorities and third sector and patient/user organisations and the WEAHSN actively engaging in the conduct of applied health research and the implementation of relevant research evidence to improve health and healthcare across the area	Professor Jenny Donovan (Director)	<a href="mailto:clahrcwest@nhr.ac.uk">clahrcwest@nhr.ac.uk</a>

## 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 applicable)**

	CTIMPs (indicate Phases)	Clinical Trial of a Medical Device	Other Clinical Studies	Human Tissue: Tissue Samples Studies	Study Administering Questionnaires	Qualitative Study	OTHER
As Sponsoring Organisation	II, III, IV, post marketing	Yes	Yes	Yes	Yes	Yes	
As Participating Organisation	II, III, IV, post marketing	Yes	Yes	Yes	Yes	Yes	Phase I non-healthy volunteer CTIMPs will be considered
As Participant Identification Centre	I, II, III, IV, post marketing	Yes	Yes	Yes	Yes	Yes	

Which licences does the organisation hold which may be relevant to research?

Organisation Licences	
Licence Name Example: Human Tissue Authority Licence	Licence Details
Human Tissue Authority Licences	<p>Licensed Premises: North Bristol NHS Trust Licence Number: 40048 (Main licence) for Organ donation and transplantation Licence Number: 12608 (Satellite licence) for Research</p> <p>Licensed Premises: Southmead Hospital Number: 11143 (Main licence) for Human Application Licence Number: 12413 (Main licence) for Post mortem</p>
Pharmacy Licences	<p>MHRA Licence Type: Wholesale Distribution Authorisation (Human) (WDA(H)) MHRA Licence Number: 18524</p> <p>Registered as a pharmacy premises with the General Pharmaceutical Council. Pharmacy registration number: 1102486</p>

### Organisation Services

Information on key clinical services contacts and facilities/equipment which may be used in studies for supporting 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 within Service Department	Contact email	Contact number	Details of any internal agreements
Pathology	<ul style="list-style-type: none"> <li>Bristol Genetics Laboratory</li> <li>Cellular Pathology</li> <li>Clinical Biochemistry</li> <li>Haematological Malignancy Diagnostics</li> <li>Haematology</li> <li>Immunology and Immunogenetics</li> <li>Microbiology and Virology</li> </ul>				<p>Agreements and co-ordination processed through Research &amp; Innovation department</p>
Medical Photography & Illustration	<ul style="list-style-type: none"> <li>Clinical photography</li> <li>Clinical video</li> <li>Fundoscopy</li> </ul>				
Radiology	<ul style="list-style-type: none"> <li>X-Ray</li> <li>MRI</li> <li>CT</li> <li>Ultrasound</li> <li>Nuclear Medicine</li> <li>Interventional Radiology/Fluoroscopy</li> </ul>				
Laser Center	<ul style="list-style-type: none"> <li>Pulse dye laser</li> <li>KTP laser</li> <li>Qswitched NdYAG laser</li> <li>Qswitched Ruby laser</li> <li>Long pulsed Alexandrite laser</li> <li>Long pulsed NdYAG laser</li> </ul>				
Pharmacy	Dedicated Research Pharmacist supported by Pharmacy Assistant				
Clinical Research Centre (CRC)	CRC brings together researchers from all disciplines from across the Trust enabling them to work closer together to share best practice and to collaborate on research projects				
			Contact Research & Innovation department: Tel: 0117 414 9330; Email: research@nbt.nhs.uk		

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

Management Support e.g. Finance, Legal Services, Archiving				
Department	Specialist services that may be provided	Contact Name within Service Department	Contact details	Details of any internal agreement templates
Archiving	Support with archiving of closed research studies	Referral to external provider - Iron Mountain		R&I has contract with external provider for research archiving. Archiving is governed by a Standing Operating Procedure.
	Support with NBT medical records	Medical Records department		

Finance	Advice on costing and management of research projects	Research Costing Accountant
Contracts/Legal	Legal advice on research contracts and other issues	Commercial and Legal Services Manager
Information Governance/ Data Management support	Advice on data management	Head of Information Governance
Information Technology	Support using EDGE database	Referral to external EDGE provider - University of Southampton

Contact Research & Innovation department:  
Tel: 0117 414 9330; Email: [research@nbt.nhs.uk](mailto:research@nbt.nhs.uk)

National NIHR costing templates used.
National NIHR contract templates used.

	Support with other NBT IM&T systems	IT Help Desk	
Personnel	Support with recruitment process and access arrangements	Human Resources department	National Research Passport documentation used.
Statistical Support	Statistical support and advice	Referral to external provider - University of the West of England, Bristol statistics service	R&I has contract with external provider for statistical support.

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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
Diabetes:	The dedicated research team has an outstanding record in study delivery. Winners of the coveted Pharmaceutical Times Clinical Research Site of the Year award. The team have established innovative relationships with GP practices to help ensure every study is able to recruit to time and target.	Please see website: <a href="http://www.nbt.nhs.uk/research">www.nbt.nhs.uk/research</a>
Respiratory:	With over 15 years of commercial and non-commercial research. The team excel at delivering complex interventional studies. They are currently delivering both multi-national studies at North Bristol NHS Trust and leading several complex multi-centre studies within the UK.	Please see website: <a href="http://www.nbt.nhs.uk/research">www.nbt.nhs.uk/research</a>
Urology:	Having delivered clinical excellence and research innovation working collaboratively with both drug and device companies, the North Bristol NHS Trust urology department now delivers the clinical service for the whole Bristol area increasing both our clinical and research potential. The department has an enviable position focussing world leading clinicians, dedicated research staff and a patient population invested in the development of future treatment options.	Please see website: <a href="http://www.nbt.nhs.uk/research">www.nbt.nhs.uk/research</a>
Trauma:	The Trauma Research team undertake both commercial and non-commercial, national and international, device and cIMP studies. An integral part of South West Regional Trauma Centre based at NBT, this highly skilled team are able to include patients in the crucial early phases post traumatic injury in a sensitive and caring manner.	Please see website: <a href="http://www.nbt.nhs.uk/research">www.nbt.nhs.uk/research</a>
Neurosciences:	Our neurosciences service is world leading in a number of clinical and research specialities include stroke, dementia, Parkinson's disease, multiple sclerosis and Huntington's disease. They work with National Institute for Health Research (NIHR) networks to deliver research excellence for patients with complex and varied needs.	Please see website: <a href="http://www.nbt.nhs.uk/research">www.nbt.nhs.uk/research</a>
Renal:	North Bristol NHS Trust is a centre of excellence for the delivery of care for people with renal impairment. Our experienced research team works collaboratively with a number of other research teams including diabetes and cancer to deliver cross-functional complex studies in addition to studies focused solely within the renal service.	Please see website: <a href="http://www.nbt.nhs.uk/research">www.nbt.nhs.uk/research</a>
Musculoskeletal:	The Bristol University School of Clinical Sciences musculoskeletal research team are based at North Bristol NHS Trust. This partnership enables clinicians and researchers to closely collaborate both locally and internationally to deliver high quality research based on our multidisciplinary expertise. The Avon Orthopaedic Centre has a long history of being one of the leading centres in the country for research and innovation in orthopaedic care.	Please see website: <a href="http://www.nbt.nhs.uk/research">www.nbt.nhs.uk/research</a>
Infection:	The Trust's research group in antimicrobial chemotherapy (BCARE) have a track record spanning 45 years of excellence and international and national leadership in antibacterial therapeutics. In recent years this has expanded to encompass the impact of diagnostics on clinical outcomes. The Group have numerous links to commercial funders and an extensive international network of research collaborators.	Please see website: <a href="http://www.nbt.nhs.uk/research">www.nbt.nhs.uk/research</a>
Breastcare:	The Breastcare Centre at North Bristol NHS Trust offers patients, and people at risk of developing breast cancer, excellent patient centered care and the opportunity to participate in research. The centre has had a successful research team in place for a number of years delivering complex interventional studies.	Please see website: <a href="http://www.nbt.nhs.uk/research">www.nbt.nhs.uk/research</a>
Cancer:	We diagnose over 3,000 new cases of cancer and treat approximately 5000 new and recurrent cancers each year, making us one of largest cancer centres in the South West. The clinical trials team at North Bristol NHS Trust co-ordinates and support the delivery of clinical trials across a variety of cancers including, Haematology, Urology, Brain, Head & Neck, Upper Gastro Inestinal, Colorectal, Breast, Lung & Skin cancer.	Please see website: <a href="http://www.nbt.nhs.uk/research">www.nbt.nhs.uk/research</a>

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

### Specialty Group Membership (Local and National)

Details of local speciality leads can be found on the CRN website: [www.crn.nihr.ac.uk](http://www.crn.nihr.ac.uk)

## Organisation R&D Planning and Investments

Planned Investment			
Area of Investment (e.g. Facilities, Training, Recruitment, Equipment etc.)	Description of Planned Investment	Value of Investment	Indicative dates
Training, equipment and facilities	In addition to the integrated training plan, applications can be submitted for funding for additional training, equipment or facilities. Assessed by R&I Senior Team at meeting following closing date and ad hoc on a monthly basis.	8% of CRN: West of England delivery funding allocation	Bi-annual and ad hoc
Southmead Hospital Charity Research Fund	Annual call to support research projects which have direct relevance to the NHS or which sit on a translational pathway. Assessed by diverse research review panel.	Varies depending on charitable donations received annually	Annual, when sufficient funding from charitable donations available
Release of clinician time to prepare NIHR grant applications	Ad hoc applications for Research Capability Funding are submitted by researchers. Assessed monthly at R&I Senior Team meeting.	Varies depending on allocation from NIHR	Ad hoc
Research delivery infrastructure (e.g. research nurses, technicians, administrators)	Ad hoc requests submitted by researchers for resources to enable delivery of NIHR portfolio studies. Assessed monthly at R&I Senior Team meeting.	Within the constraints of CRN: West of England or grant income related to the study	Monthly

## Organisation R&D Standard Operating Procedures Register

### Standard Operating Procedures

R&I has a suite of research Standard Operating Procedures, which provide detailed guidance on all aspects of research study management from design through to completion.

The full suite of R&I SOPs can be accessed at: [www.nbt.nhs.uk/research](http://www.nbt.nhs.uk/research)

Information on the processes used for managing Research Passports

### Indicate what processes are used for managing Research Passports

#### Research Passports

Research passports are managed by the R&I office, and in accordance with the relevant R&I Standing Operating Procedure.

Information on the agreed Escalation Process to be used when R&D governance issues cannot be resolved through normal processes

### Escalation Process

In the first instance, for individual R&D governance issues the escalation process is either:

- a) Research Facilitator > NBT Clinical Trials Officer > NBT Clinical Trials Manager > Research Operations Manager > Deputy Director of Research > Director of Research / Relevant NBT Director (Medical Director; Head of Information Governance) > Chief Executive
- b) Research Infrastructure > NBT Research Matron > Research Operations Manager > Deputy Director of Research > Director of Research / Relevant NBT Director (Medical Director; Head of Information Governance) > Chief Executive

For Broader / systemic issues the escalation process is:

R&I Senior Team > Research & Innovation Group > Trust Board

## Planned and Actual Studies Register

The Organisation should maintain or have access to a current list of planned and actual studies which its staff lead or collaborate in.

### Comments

A record for every research project undertaken at NBT is held electronically by R&I. Currently R&I uses the research database, EDGE, to register and manage research projects at NBT. Confirmation of capability and capacity is managed and studies and recruitment targets are monitored through this system.

## Other Information

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

### Other Information (relevant to the capability of the Organisation)

NBT research website: [www.nbt.nhs.uk/research](http://www.nbt.nhs.uk/research)