

# NIHR Guideline B01

## R&D Operational Capability Statement

Jun-14

### Version History

Version number	Valid from	Valid to	Date approved	Approved by	Updated by
Statement 001	01/06/2014	31/05/2015	01/06/2014	Trust Board	Clinical Research Governance Manager

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### Organisation R&D management arrangements

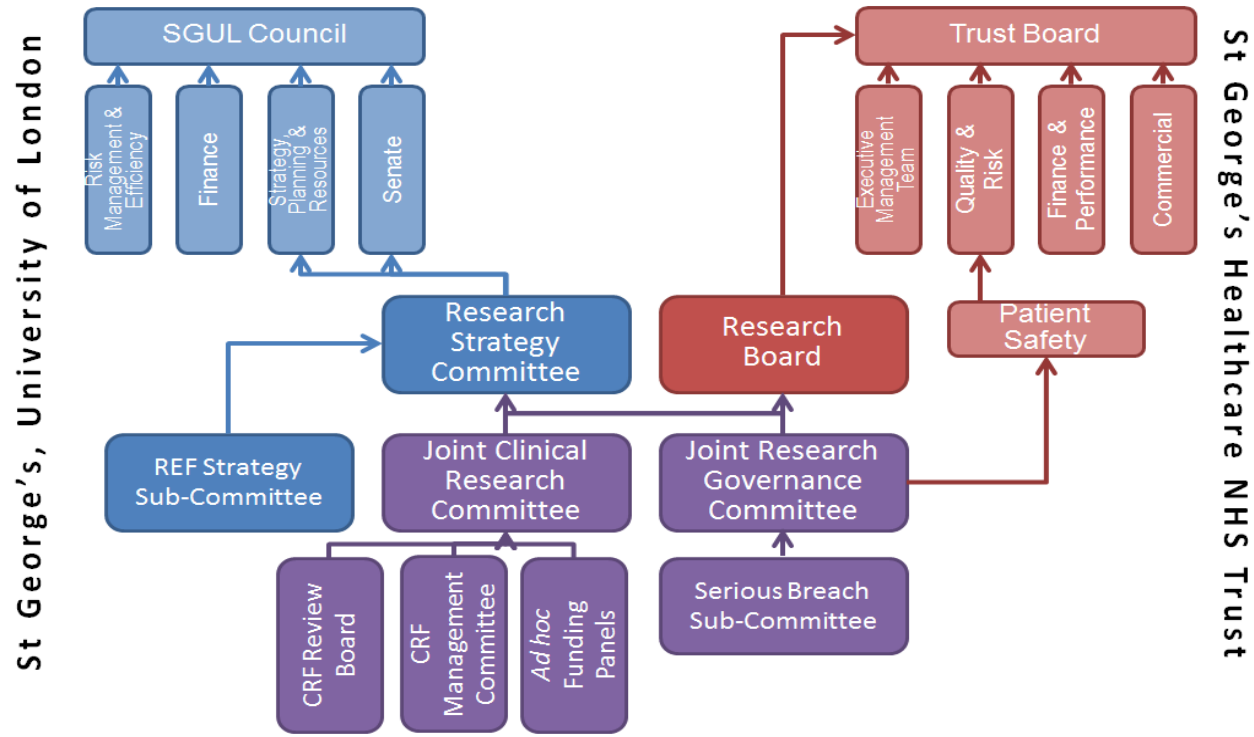
Information on key contacts.

Organisation details	
Name of organisation	St George's Healthcare NHS Trust
R&D lead / Director (with responsibility for reporting on R&D to the organisation Board)	Steff Hazlehurst, Director, Joint Research and Enterprise Office (JREO)
R&D office details:	
Name:	Joint Research and Enterprise Office
Address:	Ground Floor, Hunter Wing, Cranmer Terrace, Tooting, London, SW17 0RE
Contact number:	020 8725 4986
Contact email:	<a href="mailto:researchgovernance@sgul.ac.uk">researchgovernance@sgul.ac.uk</a> ; <a href="mailto:research@sgul.ac.uk">research@sgul.ac.uk</a> ; <a href="mailto:research@stgeorges.nhs.uk">research@stgeorges.nhs.uk</a>
Other relevant information:	
Key contact details e.g. Research governance lead, NHS Permissions signatory contact details	
Contact 1:	
Role:	Director, JREO
Name:	Steff Hazlehurst
Contact number:	020 8725 5012
Contact email:	<a href="mailto:shazlehu@sgul.ac.uk">shazlehu@sgul.ac.uk</a>
Contact 2:	
Role:	Clinical Research Governance Manager
Name:	Lucy Parker
Contact number:	020 8266 6397
Contact email:	<a href="mailto:lparker@sgul.ac.uk">lparker@sgul.ac.uk</a>
Contact 3:	
Role:	Performance Manager (NIHR)
Name:	MaryCate MacLennan
Contact number:	020 8725 5184
Contact email:	<a href="mailto:marycate.maclellan@stgeorges.nhs.uk">marycate.maclellan@stgeorges.nhs.uk</a>

Information on staffing of the R&D office.

R&D team		
R&D office roles (e.g. Governance, contracts, etc)	No of Employees	Comments indicate if shared/joint/week days in office etc
JREO Director	1	These posts are a mix of full-time and part-time.
Clinical Research Governance Manager	1	
Head of Enterprise	1	
Technology Transfer Officer	2	
Clinical Research Governance Officer	2	
Clinical Research Governance Facilitator	1	
Trust Senior Finance Manager	1	
R&D Cost Accountant	1	
Accounts Assistant	1	
Performance Manager (NIHR)	1	
Contracts Executive	1	
Regulatory Assurance Manager	1	
Clinical Trial Monitor	2	
JREO Coordinator	1	

Reporting structures



Information on research networks supporting/working with the organisation.

Research networks	
Research network (name/location)	Role/relationship of the research network e.g. host organisation
The NIHR Clinical Research Network: South London	Local NIHR Clinical Research Network

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 (e.g. university/organisation joint office, external provider of	Contact name	Email address	Contact number
Health Innovation Network (the Academic Health Science Network (AHSN) for South London)	Collaboration between a range of health service providers, universities, CCGs, the third sector and industry in South London	Dr Chris Streater, Managing Director, HIN	<a href="mailto:christ.streater@nhs.net">christ.streater@nhs.net</a>	020 7188 9805
South London Collaboration for Leadership in Applied Health Services Resesarch and Care (CLAHRC)	Collaboration between King's Health Partners, St George's Healthcare NHS Trust and St George's, University of London (along with other partners)	Professor Graham Thornicroft, CLAHRC Director	<a href="mailto:graham.thornicroft@kcl.ac.uk">graham.thornicroft@kcl.ac.uk</a>	020 7848 0736
Moorfields Eye Hospital	Research collaboration partner			02072533411
Southwest London Mental Health Trust	Research collaboration partner	Simon Eckett	<a href="mailto:simon.eckett@swlstg-tr.nhs.uk">simon.eckett@swlstg-tr.nhs.uk</a>	02035136162

## 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	I-IV	Y	Y	Y	Y	Y	Y
As participating organisation	I-IV	Y	Y	Y	Y	Y	Y
As participant identification centre	I-IV	Y	Y	Y	Y	Y	Y

Information on any licences held by the organisation which may be relevant to research.

### Organisation licences

Licence name Example: Human Tissue Authority licence	Licence details	Licence start date (if applicable)	Licence end date (if applicable)
Human Tissue Authority License no- 12462	SGHT Designated Individual Amy Gass		
Manufacturers Specials Licence	MS-12853 -MHRA site number 286009 held by Mr Vinodh Kumar	10.3.1995 current licence dated 21.9.2010	
MA IMP (Manufacturers authorisation - Investigational Medicinal Products	MIA(IMP) 12853 - MHRA site number 286009 Held by Mr Vinodh Kumar	2.12.2008 current license dated 2.3.2013	

For organisations with responsibilities for GPs: Information on the practices which are able to conduct research.

### Number/notes on General Practitioner (GP) practices

N/A

## 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 (e.g. number/type of scanners)	Contact name within service department	Contact email	Contact number	Details of any internal agreement templates and other comments
<i>Pathology</i>	The department has an extensive range of tests and services. The department is CPA accredited. For the full range of tests performed at St Georges - <a href="http://www.stgeorges.nhs.uk/gps-and-clinicians/clinical-resources/pathology/">www.stgeorges.nhs.uk/gps-and-clinicians/clinical-resources/pathology</a>		<a href="https://www.stgeorges.nhs.uk/gps-and-clinicians/clinical-resources/pathology/">https://www.stgeorges.nhs.uk/gps-and-clinicians/clinical-resources/pathology/</a>		
<i>Radiology</i>	<p>Neuroradiology -1.5T Phillips Whole Body MRI, 3T Phillips Whole Body MRI, MR compatible anaesthetic system, MRI compatible patient monitoring, RI compatible twin head injection pump, CT GE Neuro, vascular and body imaging, Angiography neuro, Xenon CT Scanner, Plain films, Radiographers trained on all modalities, consultant neuroradiologists. Radiology Capability Statement</p> <p>Radiology consists of a number of specialist services and imaging modalities detailed below. Each is managed by a superintendent radiographer, has specialised consultant radiologists and is staffed by dedicated radiographers. A number of trained staff also rotate around the modalities. Imaging output from each service is stored centrally on a Philips iSite Picture Archiving and Communication System (PACS) allowing Trust-wide access to high quality imaging. Workflow within radiology is managed by a Soliton Radiology Information System (RIS) which integrates with the OrderComms module of Cerner Millennium, our Hospital Information System (HIS) to allow electronic ordering. Reporting is facilitated using Soliton voice-recognition technology and reports are available on HIS once authorised. Imaging can be transferred to other NHS sites via the Image Exchange Portal (IEP).</p> <ul style="list-style-type: none"> <li>• • General X-Ray</li> </ul> <p>General x-ray is provided by five Philips Bucky Diagnost Computed Radiography (CR) x-ray rooms. One room has been upgraded to Digital Radiography (DR) using a Konica Minolta Aero DR retrofit. There is one dedicated DR Paediatric room with a Konica Minolta Aero DR X-70. Adult and Paediatric Fluoroscopy is performed using a Siemens Artis Zee multipurpose room. Mobile x-rays are performed by seven GE AMX4+ mobile machines or a GE AMX4 machines. Theatre work is performed using either of three Siemens Siremobile compact Image Intensifiers or three Siemens Arcadis Varic Image Intensifiers.</p>	Sarah Foote - Superintendent Neuro Radiographer Johnny Vlahos - Consultant Radiologist, Research Lead	<a href="mailto:sarah.foote@stgeorges.nhs.uk">sarah.foote@stgeorges.nhs.uk</a> <a href="mailto:Johnny.Vlahos@stgeorges.nhs.uk">Johnny.Vlahos@stgeorges.nhs.uk</a>		

<p><i>Radiology (continued)</i></p>	<ul style="list-style-type: none"> <li>• A&amp;E (Major Trauma Centre with helipad) General x-rays are acquired in two Xograph BuckyStar equipped rooms with Philips Computed Radiography readers. Resus has two ceiling mounted Wolverson x-ray tubes and one Carestream DRX Digital Radiography unit. The trauma dedicated CT scanner is a Siemens Definition Flash 128-slice system with dual-tubes and a Medrad dual headed pump injector.</li> <li>• Interventional Radiology The two labs offer both adult and paediatric interventions and are equipped with high-specification single-plane x-ray fluoroscopy systems utilising flat-panel detectors. Each also has rotational capability for 3D acquisition and laser needle guidance for improved accuracy of biopsies etc. Ultrasound guidance using contrast media and various probes is employed when appropriate and intravascular ultrasound (IVUS) capability is available. Advanced software options allow perfusion assessment of lesions and subsequent treatment optimisation. State of the art treatments are available through involvement in trialling new treatment technologies. Theatre quality air management and general anaesthetic capability are also provided. A planned interventional day-case unit will soon expand our capabilities, enhancing patient experience and throughput.</li> <li>• CT (Non-trauma) General CT acquisitions are performed by two GE Lightspeed VCT 64-slice scanners with EZEM injector systems. These have interventional (CT Fluoroscopy) capability and are equipped for patients requiring general anaesthetic.</li>   <li>• Ultrasound Ultrasound services are provided through a mixture of inpatient and outpatient configured ultrasound rooms. There are 7 high-end ultrasound systems (6 Toshiba Aplios and 1 Philips iU22) with an extensive range of transducers, to provide the fixed location service and there are 3 portable units. 6 machines have ultrasound contrast capability and two units are equipped with quantitative elastography. Services include all non-obstetric / non-breast diagnostic ultrasound (paediatrics is included in this). Targeted biopsies, fine needle aspirates are performed as an outpatient service. There is GP direct access to MSK injection service. The service is delivered by both reporting advanced practitioner sonographers and consultant radiologists.</li> <li>• Nuclear Medicine Physiological imaging is provided by three Siemens SPECT gamma cameras (an Intevo T16, an Intevo T2 and a Symbia S), the former two of which also have integrated CT capability. PET/CT scanning is currently provided via a mobile scanner. Non-imaging nuclear medicine tests (e.g. GFR measurements) are supported by a Wallac Wizard automatic gamma counter. Radionuclide therapy is also offered on an outpatient basis. Radiopharmaceuticals for the SPECT scanners and therapies are prepared in-house in a clean room environment and a Technegas generator is available for lung ventilation studies. Administration of radioactive substances to patients is performed under the supervision of three ARSAC-licence holding specialist consultant radiologists (one of whom also specialises in paediatrics) and a consultant and two senior medical physicists.</li> <li>• MRI Whole body imaging capability is acquired via a GE 1.5T scanner with MRI compatible patient monitoring and a twin head injection pump.</li> </ul>				
<p><i>Pharmacy-Research</i></p>	<p>Dedicated Research Pharmacy</p>	<p>Nia Al-Samarrai</p>	<p><a href="mailto:researchpharmacy@stgeorges.nhs.uk">researchpharmacy@stgeorges.nhs.uk</a></p>	<p>020 8725 4648</p>	
<p><i>Pharmacy</i></p>	<p>Licensed unit for manufacture and/or QP release according to conditions of MIA IMP license</p>	<p>Peter Mollison</p>	<p><a href="mailto:researchpharmacy@stgeorges.nhs.uk">researchpharmacy@stgeorges.nhs.uk</a></p>	<p>020 8725 4648</p>	
<p><i>Clinical Research Facility</i></p>	<p>Specialist staff support- Research Nurses, Data collection - Specialist Lab facilities and at a minimum Office/Clinic space</p>	<p>Josephine Studham</p>	<p><a href="mailto:crf@stgeorges.nhs.uk">crf@stgeorges.nhs.uk</a> <a href="http://crf@sgul.ac.uk">crf@sgul.ac.uk</a></p>		
<p><i>Emergency Department</i></p>	<p>Helipad for major Trauma use</p>	<p>Heather Jarman</p>	<p><a href="mailto:heather.jarman@stgeorges.nhs.uk">heather.jarman@stgeorges.nhs.uk</a></p>	<p>020 8725 1999</p>	

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 email	Contact number	Details of any internal agreement templates and other comments
Archiving	Named archivist within the JREO. Archiving governed by Standard Operating Procedures and Working Practice Documents. Off site archiving provided by a specialised provider	Jay Morjaria	<a href="mailto:researchgovernance@sgul.ac.uk">researchgovernance@sgul.ac.uk</a>	020 8725 4986	Please contact the JREO for relevant information.
Contracts/Legal		Jay Morjaria	<a href="mailto:researchgovernance@sgul.ac.uk">researchgovernance@sgul.ac.uk</a>	020 8725 4986	Please contact the JREO for relevant information.
Finance		Jay Morjaria	<a href="mailto:researchgovernance@sgul.ac.uk">researchgovernance@sgul.ac.uk</a>	020 8725 4986	Please contact the JREO for relevant information.
Statistical support		Jay Morjaria	<a href="mailto:researchgovernance@sgul.ac.uk">researchgovernance@sgul.ac.uk</a>	020 8725 4986	Please contact the JREO for relevant information.

**Organisation R&D interests**

Information on the research areas of interest to the organisation (provide detailed or summary information as appropriate).

**Organisation R&D areas of interest**

Area of interest	Details	Contact name	Contact email	Contact number
Haematology	Non-malignant haematology, sickle cell	Dr Steve Austin	<a href="mailto:steve.austin@nhs.net">steve.austin@nhs.net</a>	
Rheumatology	OA and RA	Dr Nidhi Sofat	<a href="mailto:nsofat@sgul.ac.uk">nsofat@sgul.ac.uk</a>	
Infectious Disease - TB	Dx and Rx	Tom Harrison	<a href="mailto:t.harrison@sgul.ac.uk">t.harrison@sgul.ac.uk</a>	
Infectious Disease - STIs	Dx including rapid Dx	Dr Tariq Sadiq	<a href="mailto:tsadiq@sgul.ac.uk">tsadiq@sgul.ac.uk</a>	
Infectious Disease - Molecular Diagnostics	Bacterial disease	Phil Butcher	<a href="mailto:pbutcher@sgul.ac.uk">pbutcher@sgul.ac.uk</a>	
Hepatology	Viral hepatitis	Dr Dan Forton	<a href="mailto:dforton@sgul.ac.uk">dforton@sgul.ac.uk</a>	
Epidemiology and Population Health	Respiratory population health	Prof David Strachan	<a href="mailto:d.strachan@sgul.ac.uk">d.strachan@sgul.ac.uk</a>	
Clinical Genetics	Congenital deformities	Dr Sahar Mansour	<a href="mailto:smansour@sgul.ac.uk">smansour@sgul.ac.uk</a>	
Oncology incl. Breast Scrc	Haematology: Malignant, lymphoproliferative disease, exercise and fatigue	Dr Ruth Pettengell	<a href="mailto:rpetteng@sgul.ac.uk">rpetteng@sgul.ac.uk</a>	
	I also work with Franklin Howe on imaging and therapy in primary CNS lymphoma/cancer			
	Haematology: Malignant, Multiple Myeloma	Dr Fenella Willis	<a href="mailto:fenella.willis@stgeorges.nhs.uk">fenella.willis@stgeorges.nhs.uk</a>	
	Oncology: Melanoma, Immune therapies	Prof Gus Dalglish	<a href="mailto:g.dalglish@sgul.ac.uk">g.dalglish@sgul.ac.uk</a>	
	Oncology: Malignant, Urology	Dr Lisa Pickering	<a href="mailto:lisa.pickering@stgeorges.nhs.uk">lisa.pickering@stgeorges.nhs.uk</a>	
	Oncology: Malignant, Penile cancer	Dr Matthew Perry	<a href="mailto:Matthew.Perry@stgeorges.nhs.uk">Matthew.Perry@stgeorges.nhs.uk</a>	
Paediatrics	Paediatrics - Infectious Diseases, Vaccinology	Prof Paul Heath	<a href="mailto:pheath@sgul.ac.uk">pheath@sgul.ac.uk</a>	2087255382
	Paediatrics - Infectious Diseases, Antimicrobials	Prof Mike Sharland	<a href="mailto:Mike.Sharland@stgeorges.nhs.uk">Mike.Sharland@stgeorges.nhs.uk</a>	2087255382
Nephrology	Renal Pharmacology	Dr Iain MacPhee	<a href="mailto:imacphee@sgul.ac.uk">imacphee@sgul.ac.uk</a>	
	End stage kidney disease	Dr Debasish Banerjee	<a href="mailto:debasish.banerjee@stgeorges.nhs.uk">debasish.banerjee@stgeorges.nhs.uk</a>	2087251673
Emergency Medicine, Trauma & Critical Care	Traumatic Brain Injury	Dr Colette Griffin	<a href="mailto:Colette.Griffin@stgeorges.nhs.uk">Colette.Griffin@stgeorges.nhs.uk</a>	
	Sepsis	Dr Maurizio Cecconi	<a href="mailto:maurizio.cecconi@stgeorges.nhs.uk">maurizio.cecconi@stgeorges.nhs.uk</a>	
	Acute Kidney Injury	Dr Barbara Phillips	<a href="mailto:bphilips@sgul.ac.uk">bphilips@sgul.ac.uk</a>	
	Sepsis	Dr Andrew Rhodes	<a href="mailto:andrewrhodes@nhs.net">andrewrhodes@nhs.net</a>	
	Haemodynamics- monitoring and physiology			
	Peri-operative care			
	Pharmacokinetics			
	Health services research			
	Systematic reviews and meta-analyses			



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	Specialty area (if only specific areas within group)	Contact name	Contact email	Contact number
Local - Clinical lead	Division 2 (Diabetes, stroke, cardiovascular disease, metabolic and endocrine disorders, renal disorders)	Division 2	Dr Barry Moynihan	<a href="mailto:Barry.Moynihan@stgeorges.nhs.uk">Barry.Moynihan@stgeorges.nhs.uk</a>	
Local - Clinical lead	Division 6 (Anaesthesia/peri-operative medicine and pain management, critical care, injuries/emergencies, surgery, ENT, infectious diseases/microbiology, ophthalmology, respiratory)	Division 6	Dr Maurizio Cecconi	<a href="mailto:maurizio.cecconi@stgeorges.nhs.uk">maurizio.cecconi@stgeorges.nhs.uk</a>	
Local - Clinical lead	Division 2	Cardiovascular	Prof Abhiram Prasad	<a href="mailto:aprasad@sgul.ac.uk">aprasad@sgul.ac.uk</a>	
Local - Clinical lead	Division 6	Respiratory	Prof Emma Baker	<a href="mailto:ebaker@sgul.ac.uk">ebaker@sgul.ac.uk</a>	
Local - Clinical lead	Division 6	Critical Care	Dr Barbara Phillips	<a href="mailto:barbara.phillips@stgeorges.nhs.uk">barbara.phillips@stgeorges.nhs.uk</a>	

### Organisation R&D planning and investments

Area of investment (e.g. Facilities, training, recruitment, equipment etc.)	Description of planned investment	Value of investment	Indicative dates
Research Sabbatical PA's	Annual round to support the academic development of research active consultants	up to £100,000 annually	2013-2018
Clinical fellowship	Proposed investment in new clinical fellows	up to £100,000 annually	2014-2018
CLAHRC	Funding from the NIHR to advance the themes of the CLAHRC, and supported by match funding from the partners. The distribution of funds across	£18m over 5 years (£9m from NIHR and £9m from partners)	January 2014 - December 2019

## Organisation R&D standard operating procedures register

### Standard operating procedures

SOP ref number	SOP title	SOP details	Valid from	Valid to
		Research related Standard Operating Procedures are developed by the JREO and are posted on our web page at <a href="https://portal.sgul.ac.uk/research/research-office">https://portal.sgul.ac.uk/research/research-office</a>		

Information on the processes used for managing research passports.

#### Indicate what processes are used for managing research passports

The JREO has a clearly defined Standard Operating Procedure on Research Passports. Research Passport contact and further information: **Lucy Parker** [lparker@sgul.ac.uk](mailto:lparker@sgul.ac.uk)

Information on the agreed escalation process to be used when R&D governance issues cannot be resolved through normal processes.

#### Escalation process

The issue would be referred to Troika (comprising of the Dean of Research, Associate Medical Director (Research) and the Director of the JREO) for referral to the Joint Research Governance Committee and onward to the Research Board if necessary

## 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 in which they are involved.

### Comments

All planned and actual 'live' studies are recorded in full detail on the Joint Research and Enterprise Office 'ReDA' database.

## Other information

For example, where information can be found about the publications and other outcomes of research which key staff have led or have otherwise contributed.

### Other information (relevant to the capability of the organisation)

