

<b>TRUST BOARD IN PUBLIC</b>	<b>Date: 29<sup>th</sup> November 2012</b>	
	<b>Agenda Item: 2.6</b>	
<b>REPORT TITLE:</b>	Research & Development Operational Capability Statement (RDOCS)	
<b>EXECUTIVE SPONSOR:</b>	Dr Des Holden Medical Director	
<b>REPORT AUTHOR:</b>	Anne Shears SaSH R&D manager	
<b>REPORT DISCUSSED PREVIOUSLY:</b> (name of sub-committee/group & date)	Annual statement	
<b>Purpose of the Report and Action Required:</b> (√)		
The Board is asked to approve the R&D operational capability statement.	<b>Approval</b>	√
	<b>Discussion</b>	
	<b>Information/Assurance</b>	√
<b>Summary: (Key Issues)</b>		
<p>The RDOCS sets out the Trust Board's commitment to health R&amp;D, identifies the key roles and responsibilities of individuals governing the research agenda, and lists the external research partners (research and clinical networks). It is a CQC requirement that a healthcare organisation engaging in research has an operational capability statement and this has been compiled using a standard HIHR/ DH tool.</p>		
<b>Relationship to Trust Corporate Objectives &amp; Assurance Framework:</b>		
<p>Objective 1: safe, high quality care Objective 3: delivering an effective organisation</p>		
<b>Corporate Impact Assessment:</b>		
<b>Legal and regulatory implications</b>	Complies with CQC expectation	
<b>Financial implications</b>	Generates income from CLRN	
<b>Patient Experience/Engagement</b>	Promotes patient experience/ engagement	
<b>Risk &amp; Performance Management</b>	Reputational risk from non-participation in R&D	
<b>NHS Constitution/Equality &amp; Diversity/Communication</b>	none	
<b>Attachments:</b>		
Appendix – R&D Capability Statement		

# R&D Operational Capability Statement

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<b>Date</b>	August 2012
<b>Author</b>	Anne Shears, R&D Manager
<b>Audience</b>	Trust Board Members

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## Overview for Trust Board

### Background

The R&D Operational Capability Statement (RDOCS) sets out an Organisation's (e.g. NHS Trust) commitment to health R&D and the roles and responsibilities of those in the organisation in delivering those commitments. The RDOCS template is part of a package of National Institute of Health Research (NIHR)/Department of Health approved guidance and toolkits (Research Support Services Framework) designed to encourage good practice and support NHS research management and governance processes. The NHS R&D Office is a Trust's focal point for research; it coordinates its management of the business risk of R&D, but cannot do that in isolation. The NIHR requires each organization to adopt the Framework as a standard approach (since April 2011).

### Purpose of RDOCS

- Facilitates organisational ownership of its R&D business and Board level understanding of who is taking responsibility
- Provides an overview of the organisations current capabilities (will provide clear information to potential sponsors, research partners, investigators and NIHR about what can and what cannot be done)
- Will support improved communications, processes and improving outcomes
- Provides the R&D Manager with a Board approved framework for working with service managers and research investigators in a timely way
- Will support development of a plan for building operational capability and achieving increased research activity in order to meet national targets
- The Department of Health expects NHS organisations to publish an operational capability statement

### Process for management of updates to RDOCS

- RDOCS updates are reviewed by the R&D Committee. Committee has approved 12/07/12 draft.
- Minor amendments (named contacts and equipment) are approved by R&D committee only.
- Annual review and approval by the Trust Board.
- Board approved RDOCS will be uploaded onto the Dept. Health(NIHR) website

<http://www.nihr.ac.uk/systems/Pages/OperationalCapabilityStatements.aspx>

# NIHR Guideline B01

## R&D Operational Capability Statement - Surrey & Sussex Healthcare NHS Trust

### Version History

Version number	Valid from	Valid to	Date approved	Approved by	Updated by
RDOCS 001	01/03/2011	30/06/2011	24/03/2011	Trust Board	A Shears
RDOCS 002	01/07/2011	18/09/2011	11/08/2011	R&D Committee	A Shears
RDOCS 003	19/09/2011	11/07/2012	06/10/2011	R&D Committee	A Shears
RDOCS 004	12/07/2012			Trust Board	A Shears

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 Organisation R&D Planning and Investments  
 Organisation R&D Standard Operating Procedures Register  
 Planned and Actual Studies Register  
 Other Information

### Organisation R&D Management Arrangements

Information on key contacts

Organisation Details	
Name of Organisation	Surrey & Sussex Healthcare NHS Trust
R&D Lead / Director (with responsibility for reporting on R&D to the Organisation Board)	Dr Des Holden, Medical Director
R&D Office details:	
Name:	Mrs Anne Shears
Address:	Room AD10a Post Graduate Education Centre and Trust Headquarters, East Surrey Hospital, Canada Avenue RH1 5RH
Contact Number:	01737 768511 extn 6217
Contact Email:	<a href="mailto:anne.shears@sash.nhs.uk">anne.shears@sash.nhs.uk</a>
Other relevant information:	The R&D office facilitates and governs research activity undertaken in SASH led clinical areas within East Surrey Hospital, Crawley Hospital and Horsham Hospital. The office also manages some core CLRN governance activities on behalf of the Surrey & Sussex Comprehensive Local Research Network(CLRN)
Key Contact Details e.g. Research Governance Lead, NHS Permissions Signatory contact details	
Contact 1:	
Role:	(Medical Director and) Trust Lead for R&D - NHS Permission signatory
Name:	Dr Des Holden
Contact Number:	01737 768511 extn 1770
Contact Email:	<a href="mailto:des.holden@sash.nhs.uk">des.holden@sash.nhs.uk</a>
Contact 2:	
Role:	R&D Manager - NHS Permission signatory in Medical Director absence (not CTIMPS)
Name:	Mrs Anne Shears
Contact Number:	01737 768511 extn 6217
Contact Email:	<a href="mailto:anne.shears@sash.nhs.uk">anne.shears@sash.nhs.uk</a>
Contact 3:	
Role:	Research Governance Officer - Research Governance and Governance systems lead
Name:	Mrs Samantha Clueit
Contact Number:	01737 768511 extn 6843
Contact Email:	<a href="mailto:samantha.clueit@sash.nhs.uk">samantha.clueit@sash.nhs.uk</a>

<b>Contact 4:</b>	
Role:	Senior Research Nurse Manager - Manages Research Nurses and Research Assistants
Name:	Mrs Louise Nimako
Contact Number:	01737 768511 extn 2804
Contact Email:	<a href="mailto:louise.nimako@sash.nhs.uk">louise.nimako@sash.nhs.uk</a>
<b>Contact 5:</b>	
Role:	Chairman of Research & Development Committee
Name:	Dr Des Holden
Contact Number:	contact via R&D office or Medical Directors PA (extn 1770)
Contact Email:	<a href="mailto:des.holden@sash.nhs.uk">des.holden@sash.nhs.uk</a>
<b>Contact 6:</b>	
Role:	
Name:	
Contact Number:	
Contact Email:	

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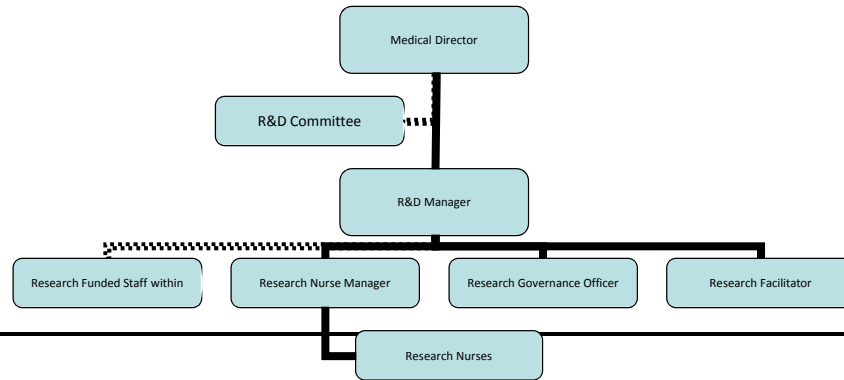
Information on staffing of the R&D Office

<b>R&amp;D Team</b>		
R&D Office Roles (e.g. Governance, Contracts, etc)	Whole Time Equivalent	Comments indicate if shared/joint/week days in office etc
Research & Development Manager	0.8	(mon - thurs). Provides strategic direction and management of research manpower resources and finances. Represents Trust on all regional Research Boards and Committees e.g. Surrey & Sussex Comprehensive Research Network (SSCLRN) Board
Research Governance Officer	0.9	(mon- fri) Manages Research Governance processes for all research activity at Trust, including contracts. Also works with CLRN Core team to provide some governance support for other Trusts within Surrey & Sussex CLRN
Research Facilitator	1	Facilitates research feasibility and study set up. Supports patient recruitment processes.

Information on reporting structure in organisation (include information on any relevant committees, for example, a Clinical Research Board / Research Committee / Steering Committee.)

**Reporting Structures**

The R&D Committee manages research activity on behalf of the Trust and is accountable to the Trust Management Board. The R&D Committee is chaired by the Trust Lead for R&D and its membership includes representatives of all service support departments and active clinical research areas. The committee meets monthly to review research activity and quarterly to agree research strategy, priorities and use of resources. All decisions on sponsorship of research are made by the R&D Committee, which also has oversight of NHS Permission powers delegated to the R&D Lead or R&D Manager.



Information on Research Networks supporting/working with the Organisation.

Information on how the Organisation works with the Comprehensive Local Research Network (CLRN), Primary Care Research Network (PCRN), Topic Specific Clinical Research Networks (TCRN).

**Research Networks**

Research Network (name/location)	Role/relationship of the Research Network eg host Organisation
Surrey & Sussex Comprehensive Local Research Network (SSCLRN)	SASH is a member Trust of the SSCLRN; appoints a representative for the SSCLRN Board and works with other member organisations to facilitate increased NIHR research activity and to standardise governance arrangements. The SSCLRN provides the bulk of SASH research income used to support research posts, research service support costs and governance costs
Surrey, West Sussex and Hampshire (SWSH) Cancer Research Network	SASH is represented on the SWSH Cancer Network (CN) Steering Group and R&D Manager works jointly with SWSH CN Manager to develop and support the Cancer Research portfolio at SASH. Network funds the Senior Oncology Research Nurse post and provides training and development support for all Research Nurses working on Cancer portfolio.
South East Stroke Research Network	Work together to develop and support the Stroke Research portfolio at SASH. Network provides training and development support for all Research Nurses working on Stroke portfolio projects.
North West London Diabetes Local Research Network	New established link for 2012. Work together to support and develop the Diabetes Research portfolio at SASH. Network provides training and development support for all Research Nurses working on Diabetes portfolio projects.

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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	Contact Number
SASH collaborates with Industry sponsors of high quality clinical trials. Collaboration is agreed on a case by case basis ( each individual research study)				
All Member organisations of SSCLRN	Work together to share good practice, support training and development of research staff, standardise research governance arrangements and unblock barriers to research activity across the region.	Anne Shears	<a href="mailto:anne.shears@sash.nhs.uk">anne.shears@sash.nhs.uk</a>	01737 768511 extn 6217

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## 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 Note re sponsorship: Sponsorship requests from Trust staff will be considered by the R&D Committee on a individual basis. The Trust requires that student projects are sponsored by their academic institution	No	No	No	No	√	√	
As Participating Organisation	Phases II - IV	√	√	√	√	√	
As Participant Identification Centre (PIC) Note re PIC studies; The Trust has very limited capacity to support PIC studies. Priority for allocation of resources will be given to studies recruiting patients at SASH.	Phases II - IV	√	√	√	√	√	

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

Organisation Licences			
Licence Name	Licence Details	Licence Start Date (if applicable)	Licence End Date (if applicable)
Example: Human Tissue Authority Licence			
Human Tissue Authority Licence	For diagnostic purposes (Pathology) and for Operating Theatres. Licences held are for diagnostic and clinical care purposes only and do not cover the storage of tissues donated for research purposes only		

## 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.

<b>Clinical Service Departments</b>					
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 agreement templates and other comments
<i>Service department support for new research studies - <b>all initial enquiries are to be raised through R&amp;D Office</b>. The R&amp;D office will consult with service department leads as part of the formal study feasibility process</i>					
Pathology	Blood and Tissue analysis	Mike Rayment	<a href="mailto:Michael.rayment@sash.nhs.uk">Michael.rayment@sash.nhs.uk</a>	01737 231894	R&D Feasibility Form.
Pathology (HTA related only)	Guidance on use of Human Tissues for research purposes and clarification on Human Tissue Authority requirements.	Liz Berry	<a href="mailto:elizabeth.berry@sash.nhs.uk">elizabeth.berry@sash.nhs.uk</a>	01737 768511 extn	R&D Feasibility Form
Radiology	Availability of imaging facilities- including MRI.	Andrew Millard	<a href="mailto:Andrew.millard@sash.nhs.uk">Andrew.millard@sash.nhs.uk</a>	01737 768511 extn 1602	R&D Feasibility Form
Radiology (Ionising Radiation and IRMER regs)	Guidance on compliance with legislation on research radiation exposure (IRMER and ARSAC)	Dr Chandani Thorning	<a href="mailto:chandani.thorning@sash.nhs.uk">chandani.thorning@sash.nhs.uk</a>	01737 768511 extn 2864	R&D Feasibility Form
Pharmacy	Clinical Trial pharmacy team providing facilities for, and guidance on, management of clinical trials	Yasmin Begum	<a href="mailto:yasmin.begum@sash.nhs.uk">yasmin.begum@sash.nhs.uk</a>	01737 768511 extn 6164	R&D Feasibility Form. NOTE: SASH does not have aseptic facilities on site. Limited provision is available by use of an external provider (requirements will be reviewed during feasibility process)
Cardiology Services (ECG)	ECG	Rachel Danvers	<a href="mailto:rachel.danvers@sash.nhs.uk">rachel.danvers@sash.nhs.uk</a>	01737 768511 extn 1661	R&D Feasibility Form
Electroencephalography(EEG)	EEG	Andrew Millard	<a href="mailto:Andrew.millard@sash.nhs.uk">Andrew.millard@sash.nhs.uk</a>	01737 768511 extn 1602	R&D Feasibility Form

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

<b>Management Support e.g. Finance, Legal Services, Archiving</b>					
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	Facilities for archiving research project information - under development. Any requests to be directed to Research Governance Officer	Sam Colley, R&D Office	<a href="mailto:samantha.clueit@sash.nhs.uk">samantha.clueit@sash.nhs.uk</a>	01737 768511 extn 6843	
Contracts	Reviewing and negotiating contracts	Sam Colley, R&D Office	<a href="mailto:samantha.clueit@sash.nhs.uk">samantha.clueit@sash.nhs.uk</a>	01737 768511 extn 6843	For externally sponsored studies only
Data management support	Support with collating and inputting research data ( available for NIHR research only)	Anne Shears, R&D Office	<a href="mailto:anne.shears@sash.nhs.uk">anne.shears@sash.nhs.uk</a>	01737 768511 extn 6217	
Finance	Costing of research and the management of research income			01737 768511 extn 6240	
Information Technology and Information Governance	Guidance on electronic processing of information on research participants	Dipa Bhella	<a href="mailto:dipa.bhella@sash.nhs.uk">dipa.bhella@sash.nhs.uk</a>	01737 768511 extn	
Legal	Any requests to be directed to R&D Manager.	Anne Shears, R&D Office	<a href="mailto:anne.shears@sash.nhs.uk">anne.shears@sash.nhs.uk</a>	01737 768511 extn 6217	
HR - Medical Staffing	Guidance on and provision of consultant contracts	Nisha Patel	<a href="mailto:Nisha.patel@sash.nhs.uk">Nisha.patel@sash.nhs.uk</a>	01737 768511 extn 1772	
Statistical support	Via the Research Design Service South East		web link : <a href="http://www.rds-se.nihr.ac.uk/">http://www.rds-se.nihr.ac.uk/</a>		Only available for researchers seeking competitive national funding for their project

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## Organisation R&D Interests

Information on the areas of research interest to the Organisation

### Organisation R&D Areas of Interest

The Trust has CLRN/NCRN funded research nurses who support NIHR studies within the following interest areas. Initial contact regarding support for new studies should be made via the R&D Manager or Senior Research Nurse Manager

Area of Interest	Details	Contact Name	Contact Email	Contact Number
Oncology ( including Haematology)	Research Nurse	Samantha Weller	<a href="mailto:samantha.weller@sash.nhs.uk">samantha.weller@sash.nhs.uk</a>	
Diabetes	Research Nurse	Louise Nimako	<a href="mailto:louise.nimako@sash.nhs.uk">louise.nimako@sash.nhs.uk</a>	
Paediatrics	Research Nurse	Linda Bailey	<a href="mailto:linda.bailey@sash.nhs.uk">linda.bailey@sash.nhs.uk</a>	
Rheumatology	Research Nurse	Stephanie Allen	<a href="mailto:stephanie.allen@sash.nhs.uk">stephanie.allen@sash.nhs.uk</a>	
Dermatology	Research Nurse	Louise Nimako	<a href="mailto:louise.nimako@sash.nhs.uk">louise.nimako@sash.nhs.uk</a>	
Cardiology	Research Nurse	Sally Collins	<a href="mailto:sally.collins@sash.nhs.uk">sally.collins@sash.nhs.uk</a>	
Stroke	Research Nurse	Andrea Jolly	<a href="mailto:andrea.jolly@sash.nhs.uk">andrea.jolly@sash.nhs.uk</a>	
Health Care of Older People	Research Nurse	Stephanie Allen	<a href="mailto:stephanie.allen@sash.nhs.uk">stephanie.allen@sash.nhs.uk</a>	
Reproductive Health	Research Nurse	Linda Bailey	<a href="mailto:linda.bailey@sash.nhs.uk">linda.bailey@sash.nhs.uk</a>	
Orthopaedics	Research Nurse	Stephanie Allen	<a href="mailto:stephanie.allen@sash.nhs.uk">stephanie.allen@sash.nhs.uk</a>	

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

### Specialty Group Membership (Local and National)

Trust clinicians are invited to attend local speciality groups. The following contacts have confirmed group membership for their areas of speciality

National / Local	Specialty Group	Specialty Area (if only specific areas within group)	Contact Name	Contact Email	Contact Number
Local	Stroke		Youssif Abousleiman	<a href="mailto:Youssif.abousleiman@sash.nhs.uk">Youssif.abousleiman@sash.nhs.uk</a>	
Local	Paediatrics		Catherine Greenaway	<a href="mailto:catherine.greenaway@sash.nhs.uk">catherine.greenaway@sash.nhs.uk</a>	
Local	Diabetes and Endocrinology		Ben Field	<a href="mailto:benjamin.field@sash.nhs.uk">benjamin.field@sash.nhs.uk</a>	

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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	Value of Investment	Indicative dates
Training for researchers	The Trust runs regular training sessions on good clinical practice for research, which all research active staff are required to attend.	£3000 per annum	Courses run up to 4 times per annum. Details available from R&D office
IT Facilities	Upgrade of PC software facilities (in areas supporting research) to facilitate set up of new national research databases (RDMIS). Will allow wider access to data by service support departments and research active clinical staff as well as R&D office	up to £4000	2011/2012
Pathology facilities (investment required to upgrade facilities to supporting increased research)	Review of facilities to be undertaken by recently appointed Pathology Research Co-ordinator		From October 2012
Recruitment of additional research staff	Additional Research Nurses to support planned growth in research activity	£60,000	during 2012
Office space for research staff	Additional office space required for Research Support staff (nurses and admin) to support increasing research activity	£5,000	2011/ 2012

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## Organisation R&D Standard Operating Procedures Register

Standard Operating Procedures				
SOP Ref Number	SOP Title	SOP Details	Valid from	Valid to
	The R&D Office maintains details of Research Standard Operating Procedures (SOPs). These are reviewed and updated as necessary and will be in line with the NIHR Research Support Services guidelines			

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Information on the processes used for managing Research Passports

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

SASH follows national guidance on issue of Research Passports. All research passport requests are to be forwarded to Research Governance Officer who will organise the passport as part of the R&D approval processes

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

#### **Escalation Process**

Issues on Research governance will normally be resolved within the R&D department. Unresolved issues are to be brought to the attention of the Medical Director who may wish to involve the R&D Committee in achieving resolution.

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### **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**

The R&D department maintain details of all research activity on the RADOS database

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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 collaborated in?

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

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