

# NIHR Guideline B01

## R&D Operational Capability Statement

### Version History

Version number	Valid from	Valid to	Date approved	Approved by	Updated by
RDOCS 001	31/03/2011	31/03/2012		Clinical Board	Catherine Holley
RDOCS 002	31/03/2013	31/03/2014		Clinical Board	Liz Still

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### Organisation R&D Management Arrangements

Information on key contacts

Organisation Details	
Name of Organisation	East Sussex Healthcare NHS Trust
R&D Lead / Director (with responsibility for reporting on R&D to the Organisation Board)	Clinical Lead for Research and Development; Dr Sam Panthakalam
R&D Office details:	
Name:	Liz Still, Research and Development Manager
Address:	East Sussex Healthcare Trust, Clinical Research Department, Polegate Ward, Eastbourne District General Hospital, Kings Drive, Eastbourne, East Sussex, BN21 2UD
Contact Number:	01323 417400 ext 3042/ 3880. Direct line 01323 413880
Contact Email:	<a href="mailto:Liz.Still@esht.nhs.uk">Liz.Still@esht.nhs.uk</a>
Other relevant information:	
Key Contact Details e.g. Research Governance Lead, NHS Permissions Signatory contact details	
Contact 1:	
Role:	Clinical Lead for Research and Development
Name:	Dr Sam Panthakalam
Contact Number:	01323 41400 Ext 3714
Contact Email:	<a href="mailto:sam.panthakalam@esht.nhs.uk">sam.panthakalam@esht.nhs.uk</a>
Contact 2:	
Role:	Associate Medical Director for Academia, Education and Research - Chair Research and Development Steering Group, NHS Permissions Signatory
Name:	Dr Harry Walmsley
Contact Number:	01323 417400
Contact Email:	<a href="mailto:walmsley.harry@esht.nhs.uk">walmsley.harry@esht.nhs.uk</a>
Contact 3:	
Role:	Research Support Manager
Name:	Liz Still
Contact Number:	01323 417400 ext 3880. Direct line 01323 413880
Contact Email:	<a href="mailto:Liz.Still@esht.nhs.uk">Liz.Still@esht.nhs.uk</a>
Contact 3:	
Role:	Research Governance Co-Ordinator
Name:	Teresa Baumber
Contact Number:	01323 417400 ext 3042
Contact Email:	<a href="mailto:teresa.baumber@esht.nhs.uk">teresa.baumber@esht.nhs.uk</a>

Add further contacts by selecting and then **copying** the five Excel **rows** (ie whole rows) above for Contact, role, name, number and email.

Then select the **blank row** under the table and 'insert copied cells'. (Please do not select and copy individual cells or groups of cells as this does not preserve formatting.)

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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 and Development Manager	1	
Research Governance Co-Ordinator	1	
Research Administrator	1	TBC

Add lines in the table as required by selecting and then copying a whole Excel row which is a part of the table (note: select and copy the row **not** cells in the row). Then select a **row** in the table and 'insert copied cells'. (Please do not select and copy individual cells or groups of cells as this does not preserve formatting.)

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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.)

<b>Reporting Structures</b>
<p>The Research and Development Steering Group fulfils the committee requirements within the organisation. It is comprised of representation from Consultant Clinicians within clinical specialities, support services, R&amp;D management team and Lead Research Nurse. It is the steering organisation for the R&amp;D department. The R&amp;D Steering Group makes decisions on funding, CTIMP sponsorship, strategy and policy. The R&amp;D SG meets quarterly and reports to Management Executive via Medical Director on a quarterly basis. Annual reports are received by the Trust Board.</p> <p>An R&amp;D Operational Working Group which is comprised of the R&amp;D Management team, Governance and Accounts, meets monthly. This OWG deals with the day to day issues in R&amp;D and makes non CTIMP and student sponsorship decisions and funding decisions under £1000, as well as any urgent administrative issues that require more immediate decision making.</p>

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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), Primary Care Research Network (PCRN), Topic Specific Clinical Research Networks (TCRN).

<b>Research Networks</b>	
Research Network (name/location)	Role/relationship of the Research Network eg host Organisation
Kent, Surrey and Sussex Clinical Research Network	

Add lines in the table as required by selecting and then copying a whole Excel row which is a part of the table (note: select and copy the row **not** cells in the row). Then select a **row** in the table and 'insert copied cells'. (Please do not select and copy individual cells or groups of cells as this does not preserve formatting.)

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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)

<b>Current Collaborations / Partnerships</b>				
Organisation Name	Details of Collaboration / Partnership (eg	Contact Name	Email address	Contact Number

Add lines in the table as required by selecting and then copying a whole Excel row which is a part of the table (note: select and copy the row **not** cells in the row). Then select a **row** in the table and 'insert copied cells'. (Please do not select and copy individual cells or groups of cells as this does not preserve formatting.)

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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	✓ Phase 3+	✓	✓		✓	✓	
As Participating Organisation	✓ Phase 2+	✓	✓	✓	✓	✓	
As Participant Identification Centre	✓ Any Phase	✓	✓	✓	✓	✓	

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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	Held by Medical Director. Designated individual; Graham Rayner-General Manager, Designated persons: Shinal Amin-Lead BMS Cellular pathology and Penny Marr-		

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PCT ONLY: Information on the practices which are able to conduct research

Number/notes on General Practitioner (GP) Practices
N/A

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## 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 agreement templates and other comments
<i>Pathology / Histopathology</i>	All routine tests and ESHT can spin, separate, freeze and store samples and retrieve tissue blocks. Specialist tests are sent away for analysis. Cooled centrifuge, -80°C freezer	Clare Mullany Shinal Amin	clare.mullany@esht.nhs.uk clare.mulany@nhs.net shinal.amin@esht.nhs.uk		
<i>Radiology</i>	<b>Eastbourne:</b> Voluson Expert 730 x2 Phillips HD11 Toshiba Xario GE Logic E9 GE HD 750 CT Scanner <b>Conquest:</b> Toshiba Xario x3 Toshiba Aplio x2 Toshiba Aquillion 64 slice CT scanner GE Signa advantage 1.5T MRI scanner Bexhill: <b>Bexhill:</b> Toshiba Aplio, GE Logic 9	Christian Kasmeridis	<a href="mailto:christian.kasmeridis@esht.nhs.uk">christian.kasmeridis@esht.nhs.uk</a>	Tel. 01323 435734 (Ext.EDGH 5734/CONQ 8292)	
<i>Pharmacy</i>	Monitored Room, Refrigerator, Freezer & CD storage. Aseptic units-preparation of sterile chemotherapy products.	Mark Whitfield	Mark.Whitfield@esht.nhs.uk		

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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
<i>Archiving</i>		Medical Records / R&D			
<i>Contracts</i>	Checking contracts if required	Eanna McKnight	<a href="mailto:eanna.mcknight@nhs.net">eanna.mcknight@nhs.net</a>		Trust Solicitor
<i>Data management support</i>	Governance	Teresa Baumber	<a href="mailto:teresa.baumber@esht.nhs.uk">teresa.baumber@esht.nhs.uk</a>		
<i>Finance</i>	Financial support	John Morgan	<a href="mailto:john.morgan@esht.nhs.uk">john.morgan@esht.nhs.uk</a>		R&D Finance officer
<i>Information Technology</i>	IT assistance	Sussex HIS	<a href="mailto:sussexhiscommunications@nhs.net">sussexhiscommunications@nhs.net</a>	0845 845 4488	
<i>Legal</i>	Legal advice relating to research activities	Eanna McKnight	<a href="mailto:eanna.mcknight@nhs.net">eanna.mcknight@nhs.net</a>		Trust Solicitor
<i>HR</i>	HR support, letters of access, research passports	Janet Allison	<a href="mailto:janet.allison@esht.nhs.uk">janet.allison@esht.nhs.uk</a>		
<i>Statistical support</i>	n/a	n/a	n/a		Unable to offer at present

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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	Contact Number
Oncology	Breast,Haematology,Urology,Colorectal,Upper GI	Jo-Anne Taylor	Jo-Anne.Taylor@esht.nhs.uk	01424 755 255 ext 2003
Rheumatology		Jenny Britcher	<a href="mailto:jennifer.britcher@esht.nhs.uk">jennifer.britcher@esht.nhs.uk</a>	01323 417400 ext 3714
Cardiology		Janet Sinclair/Janet Large	<a href="mailto:janet.sinclair@esht.nhs.uk">janet.sinclair@esht.nhs.uk</a> <a href="mailto:janet.large@esht.nhs.uk">janet.large@esht.nhs.uk</a>	01424 755255 ext 8162/01323 417400 ext 3714
Stroke		Emma Barbon	<a href="mailto:emma.barbon@esht.nhs.uk">emma.barbon@esht.nhs.uk</a>	01323 417400 ext 4124
Paediatrics		Liz Foster	<a href="mailto:elizabeth.foster@esht.nhs.uk">elizabeth.foster@esht.nhs.uk</a>	01323 417400 ext 3714
Orthopaedics		Debra East	<a href="mailto:debra.east@esht.nhs.uk">debra.east@esht.nhs.uk</a>	01424 755 255 ext 8830
Ageing		Anne Cowley	<a href="mailto:anne.cowley@esht.nhs.uk">anne.cowley@esht.nhs.uk</a>	
Dermatology		Sue Tyler-Murphy	<a href="mailto:susan.tyler-murphy@esht.nhs.uk">susan.tyler-murphy@esht.nhs.uk</a>	
Gastroenterology		c/o R&D Manager	<a href="mailto:liz.still@esht.nhs.uk">liz.still@esht.nhs.uk</a>	
Anaesthetics		c/oR&D Manager	<a href="mailto:liz.still@esht.nhs.uk">liz.still@esht.nhs.uk</a>	
Diabetes		Maria Ravelo	<a href="mailto:maria.ravelo@esht.nhs.uk">maria.ravelo@esht.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)					
National / Local	Specialty Group	Specialty Area (if only specific areas within)	Contact Name	Contact Email	Contact Number

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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	Good Clinical Practice Training	Staff time	Continuous
Recruitment (to be approved)	Research Administrator	Band 4 - 1.0wte	To action

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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
SOP1	RDOCS	Version 003	to be approved	31/03/2015
SOP2	Study Planning Tool	Version 1.1	01/01/2014	01/09/2015
SOP3	Confirm study wide approval	Version 1.1	01/01/2014	01/09/2015
SOP4	Set up and control external agreements	Version 1.1	01/01/2014	01/09/2015
SOP5	Set up and control internal agreements	Version 1.1	01/01/2014	01/09/2015
SOP6	Set up and control study processes	Version 1.1	01/01/2014	01/09/2015
SOP7	Give NHS permission	Version 1.1	01/01/2014	01/09/2015
SOP8	Oversight of study including audit	Version 1.1	01/01/2014	01/09/2015
SOP9	Site study closedown.	Version 1.1	01/01/2014	01/09/2015

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Information on the processes used for managing Research Passports

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

Contact the Recruitment Manager who administers Research Passports. The key contact is Janet Allison: janet.allison@esht.nhs.uk, 01323 417400, ext 5851

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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

This would be discussed at monthly R&D Operational Working Group. If not resolved it would go to the R&D Steering Group and passed to Management Executive via Medical Director.

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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

This is kept and updated by the R&D department.

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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)

Add lines in the table as required by selecting and then copying **a whole Excel row which is a part of** the table (note: select and copy the row **not** cells in the row). Then select a **row** in the table and 'insert copied cells'. (Please do not select and copy individual cells or groups of cells as this does not preserve formatting.)

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