

NIHR Guideline B01

R&D Operational Capability Statement

Version History

Version number	Valid from	Valid to	Date approved	Approved by	Updated by
RDOCS 001	01/09/2011	31/08/2012	01/12/2000	Trust Chairman	Zoë Harris
RDOCS 002	01/06/2013	31/05/2014	07/06/2012	R&D Manager	Will Bowen

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Organisation R&D Management Arrangements

Organisation Details	
Name of Organisation	Kings College Hospital NHS Foundation Trust
R&D Lead / Director (with responsibility for reporting on R&D to the Organisation Board)	Dr Julia Wendon, Director of R&D
R&D Lead / Director (with responsibility for reporting on R&D to the Organisation Board)	Professor Tim Newton, Deputy Director of R&D
Key Contact Details e.g. Research Governance Lead, NHS Permissions Signatory contact details	
Contact 1:	
Role:	R&D Governance Specialist
Name:	Taffy Bakasa
Contact Number:	O2032991986
Contact Email:	taffybakasa@nhs.net
Contact 2:	
Role:	R&D Administrator
Name:	Gabrielle Daughtrey
Contact Number:	O2032991980
Contact Email:	kch-tr.research@nhs.net
Contact 3:	
Role:	R&D Manager
Name:	Dr Zoe Harris
Contact Number:	O2032993841
Contact Email:	z.harris@nhs.net

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R&D Team		
R&D Office Roles (e.g. Governance, Contracts, etc)	Whole Time Equivalent	Comments indicate if part time/full time/shared/joint etc
R&D Governance Officer	2	Full time
R&D Governance Specialist	1	Full time
R&D Delivery Manager	1	post vacant
R&D Facilitator	4	Full time
R&D Finance Manager	1	Full time
R&D Accountant	1	Full time
R&D Administrator	1	Full time

Reporting Structures

R&D is led within the Trust by Dr Jules Wendon. Director of R&D: Zoë Lelliott, Deputy Director, Deputy Director of Strategy,; Professor Tim Newton, Deputy Director of R&D, and Dr Zoë Harris, R&D Manager

The R&D Directors report on performance and strategy to the R&D Executive Board, a quarterly meeting chaired by Tim Smart, Chief Exective. Board members represent key areas of research within the Academic Health Sciences Centre and include Professor Simon Lovestone, Director of R&D for Kings Health Partners, Professor Anne Greenough Head of KCL school of Medicine, Professor Alan McGregor, Campus Dean and Director of the CRF/CTF, Jackie Powell, Director of the Joint Clinical Trials office (JCTO), Simon Dixon, Deputy Director of Finance.

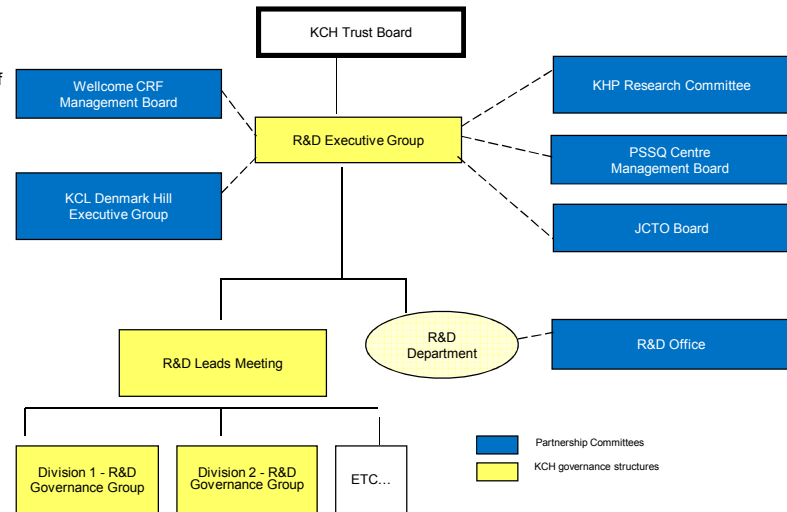
R&D is led within the clinical specialities by a group of Consultant level R&D Leads. This group of experienced clinical researchers maintain oversight for R&D governance, conduct and standards within their respective areas. This groups meets monthly with the R&D Directors

R&D approvals and permissions are conducted by the Governance Officers, with a team of R&D Facilitators providing expert advise and guidance to all investigators across the Trust. The facilitators also support the R&D Leads
Trust R&D finances for are supported by a Manager and Accountant

The Trust has a dedicated CTF and CRF, under the direction of Professor McGregor, and Elka Giemza, Nurse Manager.

KCH and KCL jointly host one of two Patient Safety and Service Quality (PSSQ) centres in the UK, under the Direction of Professors Naomi Fulop and David Guest, supported by a Alex Gaskill, Centre Manager.

KHP hosts the Joint Clinical trials Office (JCTO), under the direction of Jackie Powell, which supports the setup and facilitation of all commercial research conducted at KCH and GSTT. Jackie Pullen, Quality Manager, leads a team of CRAs who provide regulatory and monitoring support to CTIMPs sponsored by KHP.



Research Networks

Research Network (name/location)	Role/relationship of the Research Network eg host Organisation
South London CLRN	member organisation
MCRN	supports Medicines for children research
SELCRN	supports cancer research
NE London DRN	Supports diabetes research
PCRN	Supports diabetes research
South London SRN	Supports stroke research

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	Email address	Contact Number
King's Health Partners Academic Health Sciences Centre	KCH is a full partner of the DH accredited Academic Health Sciences Centre, together with SLAMFT, GSTFT and KCL	Professor Robert Lechler, Exec Director		
Guy's & St Thomas's NHS Foundation Trust (GSTT)	NHS partner within the Kings Health Partners (KHP) Academic Health Sciences Centre (AHSC). Incorporates the BRC.	Dr Kate Blake, Assistant Director of R&D Akunna Akpan, BRC Manager		
Kings College London (KCL)	NHS partner within the Kings Health Partners (KHP) Academic health sciences centre (AHSC). Collaborate on PSSQ.			
South London and The Maudsley/Institute of Psychiatry (SLAM/IoP)	NHS partner within the Kings Health Sciences (KHP) Academic health sciences centre (AHSC) Incorporates mental health BRC	Dr Gill Dale, Director of Research Quality		

King's Health Partners Clinical Trials Office (JCTO)	A collaborative office between KCL, GST and KCH within KHP. Provides support for commercial clinical trials, safety monitoring for CTIMPs sponsored within KHP	Jackie Pullen, Quality Manager (non-commercial) Alli Sellers, Contracts Advisor (commercial) Stuary Hatcher, Senior Facilitator (commercial)		
National and International collaborations within clinical and academic organisations	The Trust has a number of links with other research centres			
AHSCs and BRCs nationally	The Trust has a number of links with other research centres			
Kings Path	External joint venture between Serco, GST and KCH, providing full pathology services. Based between KCH and GST		http://kingspath.co.uk/contact	

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Organisation Study Capabilities

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	yes (mainly phase 2a/b)	yes	yes	yes	yes	yes	
As Participating Organisation	yes (mainly phase 2a/b)	yes	yes	yes	yes	yes	
As Participant Identification Centre	occasionally	occasionally	occasionally	occasionally	occasionally	occasionally	

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Organisation Licences			
Licence Name Example: Human Tissue Authority Licence	Licence Details	Licence Start Date (if applicable)	Licence End Date (if applicable)
HTA license	License number 12378, DI Dr Julia Wendon Liver research Tissue bank Institute of Liver Studies		

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Organisation Services

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
Pathology	Full pathology services		http://kingspath.co.uk/contact		
Radiology	Xray, CT, Fluoroscopy, MRI, Ultrasound			O2032999000	
Pharmacy	standard and aseptic	Rebecca Palmer R&D Principal Pharmacist	rebeccapalmer@nhs.net		

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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
Contracts	External Contracts negotiator	through the R&D office	kch-tr.research@nhs.net	02032991981	
Finance	commercial and non-commercial	Daniel Kirwan	daniel.kirwan@nhs.net	2032996641	
NIHR Statistical support	London Research Design Service		http://www.rdslondon.co.uk/		
Trust Statistical support	KCL Dept of Medical Statistics		medstats-kch@kcl.ac.uk		

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Organisation R&D Interests

Organisation R&D Areas of Interest					
Area of Interest	Details		R&D Lead	PA	Contact Email
Cancer			Steve Schey (SELCRN)		Leads can be contacted through the KCH R&D office
Cardiovascular			Phil MacCarthy	Annette Charles	
Haematology			Steve Schey		
Critical care			Phil Hopkins		
Aneasthesia			Dave Green		
Surgery and Gastro			Joydeep Sinha	Stella Fowler	
Dental Services			Tara Renton	Toni Martin	
Dermatology			Frank Post		
Diabetes & Endocrinology			Stephanie Amiel	Yvette Dow	
Endocrinology			Frank Post		
General, specialist and emergency medicince			Tariq Sethi	Julie Fuller	
Liver			Nigel Heaton	Maureen Tuohy	
Neurosciences			Ray Chaudhuri	Shelene Brown	
Ophthalmology			Frank Post		
Palliative Care			Irene Higginson	Susan Chandler	
Radiology			Paul Sidhu	Philippa Warren	
Pathology			Mohammed Ibrahim	Dorota Parsons	
Renal			Iain Macdougall	Stuart "Stu" Lindsey	
Rheumatology			Frank Post		
Sexual Health & HIV			Frank Post		
Stroke medicine			Lalit Kalra	Ann Holt	
Fetal Medicine			Nick Kametas		
Women's health			Dudley Robinson		
Child health			Anne Greenough	Candice Ebelthite	

Specialty Group Membership (Local and National)				
National / Local	Specialty Group	Specialty Group Leads at KCH	Contact Name	Contact Email
National Specialty Group Lead	Paediatrics (Non medicines)	Professor Anne Greenough		
Local	Reproductive health & childbirth		<p>Representatives for each group can be contacted through the KCH R&D office</p> <p>or</p> <p>Contact Raleen Fernandes CLRN Specialty Group Facilitator London South CLRN</p> <p>raleen.fernandes@gstt.nhs.uk</p>	
Local	Age & Aging	Professor Stephen Jackson		
Local	Anaesthesia, perioperative medicine and pain			
Local	Cardiovascular	Dr Jonathan Hill		
Local	Critical Care & Injuries & Emergencies			
Local	Dermatology			
Local	Ear, nose and throat			
Local	Gastrointestinal			
Local	Genetics			
Local	Health Services Research & Public Health			
Local	Hepatology			
Local	Immunology	Dr Mohammed Ibrahim		
Local	Infectious diseases & Microbiology			
Local	Metabolic and endocrine	Professor Stephanie Amiel		
Local	Musculoskeletal Disorders	Professor David Scott		
Local	Nervous System Disorders	Professor K Ray Chaudhuri		
Local	Non-Malignant haematology	Dr David Rees		
Local	Ophthalmology			
Local	Oral & Dental	Professor Tara Renton		
Local	Paediatrics (Non medicines)	Dr Alistair Baker		
Local	Renal	Professor Iain Macdougall		
Local	Reproductive health & childbirth			
Local	Respiratory			
Local	Surgery			

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Organisation R&D Planning and Investments

Area of Investment				
Area of Investment (e.g. Facilities, Training, Recruitment, Equipment etc.)	Description of Planned Investment			
	Value of Investment			
	Indicative dates			
Wellcome CRF/CTF				
trust funded capacity building R&D grants 2009-12				
Firefly Nanopro				
Deep Sequencer				

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Organisation R&D Standard Operating Procedures Register

Standard Operating Procedures			
SOP Ref Number	SOP Title	SOP Details	Valid from
CSP		The Trust follows the national SOP for CSP	
Research Passport		The Trust follows the national SOP for Research Passports	
IRAS		The Trust follows the national SOP for IRAS	
Departmental SOPs		The Trust is working to adopt the RSS SOPs for internal use	

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Indicate what processes are used for managing Research Passports

The Research & Development governance team follow the NIHR national guidelines for managing research passports as detailed on website, see link below:

http://www.nihr.ac.uk/systems/pages/systems_research_passports.aspx

The Governance Team ensure that the researcher is going to be working on a study that has been approved to take place at the Trust, and establishes who their substantive employer is.

The Research Passport form is used as a vehicle for providing either an honorary contract or a letter of access where the researcher is substantively employed by Higher Education Institute or another NHS Trust. The choice of honorary contract or a letter of access is established by using the Research Passport Algorithm.

The 'NHS to NHS confirmation of pre-employment checks' form is used where the researcher have a substantive employment contract with another NHS Trust.

Once the substantive employer has been established and the researcher has completed the relevant documentation a meeting is arranged with the R&D Administrator so that the documents can be reviewed and the letter issued. Once issued, copies are sent to the substantive employer, to KCH HR, and to file.

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Escalation Process

During permission process:

The R&D Governance Team are highly skilled and experienced in the permissions process and are in general able to resolve the majority of complex questions internally. Issues are identified swiftly and escalated to the R&D Manager, or appropriate R&D Lead, or clinician. If the issue remains unresolved, it is escalated further to the R&D Directors.

Research conduct:

The Trust expects all staff who conduct research to perform their duties in line with the Research Governance Framework, other relevant legislature and best practice. Training, support and advice are provided

All suspected research governance breaches should be reported through the Trust incident reporting procedure or directly to a member of the R&D team, and are investigated thoroughly and proportionately by the R&D Department.

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Planned and Actual Studies Register

We have in excess of 500+ studies actively recruiting, however this number changes daily. Please contact the R&D office for all enquiries relating to active studies and those in set-up.

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Other Information

Other Information (relevant to the capability of the Organisation)

PubMed

KCL Portal contains information on all Clinical Academic staff working with the Trust

