

NIHR Guideline B01

R&D Operational Capability Statement

Version History

Version number	Valid from	Valid to	Date approved	Approved by	Updated by
RDOCS 001	01/07/2011	31/06/2012	01/07/2011	R&D Committee	

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Organisation R&D Management Arrangements

Information on key contacts

Organisation Details	
Name of Organisation	University Hospitals of Leicester NHS Trust
R&D Lead / Director (with responsibility for reporting on R&D to the Organisation Board)	Professor David Rowbotham
R&D Office details:	
Name:	R&D Office
Address:	Leicester General Hospital, Gwendolen Road, Leicester LE5 4PW
Contact Number:	0116 258 8351
Contact Email:	
Other relevant information:	Fax: 0116 258 4226
Key Contact Details e.g. Research Governance Lead, NHS Permissions Signatory contact details	
Contact 1:	
Role:	Assistant Director of R&D
Name:	Dr David Hetmanski
Contact Number:	0116 258 4199
Contact Email:	david.hetmanski@uhl-tr.nhs.uk
Contact 2:	
Role:	R&D Manager
Name:	Mrs Carolyn Maloney
Contact Number:	0116 258 4109
Contact Email:	carolyn.maloney@uhl-tr.nhs.uk
Contact 3:	
Role:	
Name:	
Contact Number:	
Contact Email:	

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

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
Assistant Director R&D	1 WTE	
R&D Manager	1 WTE	
Clinical Trials Monitor & Trainer	1 WTE	
Senior RM&G Facilitator	1 WTE	
RM&G Facilitator	2 WTE	
R&D Administrator	1.6 WTE	
Portfolio Coordinator	1.5 WTE	
Senior Finance Manager	1.0 WTE	
Assistant Research Accountant	0.8 WTE	
Governance Manager	1.0 WTE	University of Leicester
Governance Officer	1.0 WTE	University of Leicester

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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
Trust R&D Committee (monthly): Chaired by the Trust Chairman, attended by the Chief Executive, Director of R&D, Director of Strategy, Director of Communications and External Relations, Assistant Director of Finance, Patient Advisor, Researcher from Acute Division, Researcher from Planned Care Division, Researcher from Women's & Children's Division, Researcher from Clinical Support Division, Dean of the University of Leicester Medical School, Assistant Director of R&D. Minutes of the meeting are reported to the Trust Board. Recommendations and key issues are drawn to the attention for of the Trust Board for consideration at its next meeting.

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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).

Research Networks	
Research Network (name/location)	Role/relationship of the Research Network eg host Organisation
Leicestershire, Northamptonshire & Rutland Comprehensive Local Research Network	Host Organisation
Trent Stroke Research Network	Host Organisation
South East Midlands Diabetes Local Research Network	Host Organisation
Leicestershire, Northamptonshire & Rutland Cancer Research Network	Host Organisation
Trent Local Research Children's Network	Satellite Office

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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
University of Leicester	Main academic research partner; Joint R&D Office;	Graham Hewitt	gjh13@leicester.ac.uk	0116 223 1262 or 0116 258 8241

Leicester Cardiovascular Biomedical Research Unit	Collaboration with the University of Leicester; funded by the NIHR	Tim Skelton, BRU Manager	ts144@leicester.ac.uk	0116 250 2429
Leicestershire, Northamptonshire & Rutland Collaboration for Leadership in Applied Health Research & Care	Collaboration with the University of Leicester and NHS Trusts in the LNR region; funded by the NIHR	Martin Williams, CLAHRC manager	mjw48@leicester.ac.uk	0116 252 5419
Respiratory Therapeutic Capability Cluster	As a centre with the University of Leicester in a collaboration between Pharma, academia and the NHS	Prof Chris Brightling	ceb17@leicester.ac.uk	0116 258 3340
Leicester Clinical Trials Unit	Based at the University of Leicester; collaboration between the University and the Trust; awarded provisional registration by the United Kingdom Clinical research Collaboration (UKCRC)	Dr Linda Porter	lp173@leicester.ac.uk	0116 249 4536
University Hospitals of Nottingham NHS Trust	Agreement for provision of PET Scanning by the InHealth PET Centre, Nottingham City Hospital	Contact via UHL R&D Office	rdadmin@uhl-tr.nhs.uk	0116 258 8351
University of Nottingham	Research collaboration in Respiratory Medicine and Oncology	Contact via UHL R&D Office	rdadmin@uhl-tr.nhs.uk	0116 258 8351
Loughborough University	Research collaboration in Sports & Exercise Medicine, Health Services	Contact via UHL R&D Office	rdadmin@uhl-tr.nhs.uk	0116 258 8351
De Montford University	Research collaboration in Nursing, Imaging Technology	Contact via UHL R&D Office	rdadmin@uhl-tr.nhs.uk	0116 258 8351

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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	II, II, IV	✓	✓	✓	✓	✓	
As Participating Organisation	I, II, II, IV	✓	✓	✓	✓	✓	
As Participant Identification Centre	✓	✓	✓	✓	✓	✓	

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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	The University and Trust Jointly hold an HTA Licence for Research, (Licence Number: 12384) under Section 16 (2) (e) (ii) of the Human Tissue Act 2004. The licence authorises the storage of relevant material for the following scheduled purposes: Establishing after a person's death the efficacy of any drug or other treatment administered to him; Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person); Public display; Research in connection with disorders, or the functioning of the human body; Clinical audit; Education or training relating to human health; Performance assessment; Public health monitoring; Quality assurance;		The Licence is renewed on a rolling basis each July 14th, and remains in place until revoked

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

Number/notes on General Practitioner (GP) Practices

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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</i>	UHL pathology services offer an extensive range of tests for all disciplines to both Leicestershire patients and beyond. We are a reference facility for a number of specialised tests including toxicology, Haematological Malignancy disorders, Renal Calulus analysis and Renal Biopsy histopathology to name a few. In the small number of cases where UHL pathology does not offer a test in house, then we are normally able to arrange this testing through an accredited laboratory with whom we hold a service level agreement	Mr Andrew Folwell	andrew.folwell@uhl-tr.nhs.uk	0116 204 7802	
<i>Radiology</i>	The UHL Imaging Department provides all the scanning and imaging facilities expected for a trust of this size including six CT systems (full body), five MRI systems (full body, superconducting magnets), five Gamma Camara systems and numerous basic, fluoroscopic and mammographic X-ray systems. Provision of all the above categories are provided across the three hospital sites of the Trust.	Prof Bruno Morgan	bruno.morgan@uhl-tr.nhs.uk	0116 258 6898	
<i>Pharmacy</i>	UHL Pharmacy has Trials Pharmacists covering all three hospitals of the UHL Trust, supported by a team of dedicated Trials Technicians.	Mr David Lovett	david.lovett@uhl-tr.nhs.uk	0116 258 5462	
<i>Cardiac Imaging</i>	UHL was awarded funding by the NIHR for a new dedicated 3 Tesla research scanner for Cardiovascular Magnetic Resonance (CMR) imaging. The instrument was installed at a new build on the Glenfield Hospital site in February 2011.	Dr Gerry McCann	gerry.mccann@uhl-tr.nhs.uk	0116 258 3476	

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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>		R&D Office	rdadmin@uhl-tr.nhs.uk	0116 258 8351	
<i>Contracts</i>		R&D Office	rdadmin@uhl-tr.nhs.uk	0116 258 8351	
<i>Data management support</i>		R&D Office	rdadmin@uhl-tr.nhs.uk	0116 258 8351	
<i>Finance</i>		Abdul Ismail	abdul.ismail@uhl-tr.nhs.uk	0116 258 8241	
<i>Information Technology</i>		IM&T	caroline.hughes@uhl-tr.nhs.uk	0116 258 8521	
<i>Legal</i>		Steve Murray	steve.murray@uhl-tr.nhs.uk	0116 258 8960	
<i>HR</i>		Nicola Junkin	nicola.junkin@uhl-tr.nhs.uk	0116 258 5540	
<i>Statistical support</i>		R&D Office	rdadmin@uhl-tr.nhs.uk	0116 258 8351	

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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
Cardiovascular	Genetics of coronary heart disease and development of new treatments; management of hypertension; novel therapeutic interventions for heart disease; cerebrovascular disease and stroke; cardiovascular imaging; causes and treatment of cardiac arrhythmias; cardiovascular imaging; measurement and monitoring of cardiovascular system; haemostatic mechanisms in atherothrombotic diseases; management of heart failure; vascular surgery techniques and outcomes; cardiovascular disease in ethnic minority groups.	Prof Nilesh Samani	njs@leicester.ac.uk	0116 258 3236
Diabetes	Prevention, early diagnosis, patient education and self-management; assessment of new therapies; diet, nutrition, sedentary behaviour; service development; ethnic minority groups.	Prof Melanie Davies	melanie.davies@uhl-tr.nhs.uk	0116 258 6481
Respiratory	Pathophysiology, genetics and treatment of asthma and COPD; pulmonary rehabilitation; tuberculosis; viral infections, vaccines and antiviral agents; ciliary dyskinesia (primary and chronic disease); chronic cough; emphysema surgery; extracorporeal membrane oxygenation.	Prof Chris Brightling	chris.brightling@uhl-tr.nhs.uk	0116 258 3340
Oncology	Clinical trials and development of novel chemotherapeutic agents (including those developed in our Experimental Cancer Medicine Centre laboratory); prevention of cancer; novel imaging techniques; new therapies for B cell malignancies; diagnosis and treatment of bladder and prostate cancer; novel surgical techniques.	Dr Anne Thomas	at107@leicester.ac.uk	0116 258 7602
Renal Disease	Translational, clinical and epidemiological studies in proteinuric renal disease, tubular injury, IgA nephropathy, and diabetic nephropathy; mechanisms of progressive renal injury; preventing renal disease; management of renal transplantation.	Prof Nigel Brunskill		

Child Health	National and regional infant mortality and morbidity of the fetus, infant, and child related to pregnancy, delivery, and intensive care; paediatric pharmacokinetics and pharmacodynamics; respiratory disease.	Prof David Field	df63@leicester.ac.uk	0116 258 5522
Transforming research evidence into practice	This work is conducted through the LNR CLAHRC which is hosted by UHL and includes several UHL employees as programme leads and investigators. Its purpose is to: conduct applied health research in new ways that can more rapidly inform practice; increase research capacity in the NHS so partner NHS organisations are better able to generate, and make use of, new research evidence; develop systems and structures for the application of knowledge and for the translation of research evidence into more effective and efficient health care policy and practice.	Prof Richard Baker	rb14@leicester.ac.uk	0116 252 3277
Women's Health	Urogynaecology, pre-term birth, hypertension in pregnancy; fetal-placental growth.	Mr Marwan Habiba	mah6@leicester.ac.uk	0116 258 3170

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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
Local	Age & Aging		<i>Dr Simon Conroy</i>	spc3@leicester.ac.uk	0116 252 5878
National	Age & Aging		<i>Prof Tom Robinson</i>	tom.robinson@uhl-tr.nhs.uk	0116 252 3182
Local & National	Cardiovascular		<i>Prof Nilesh Samani</i>	njs@leicester.ac.uk	0116 258 3236
Local & National	Genetics		<i>Prof Liz Draper</i>	msn@leicester.ac.uk	0116 252 3200
Local & National	Critical Care		<i>Dr Jonathan Thompson</i>	jt23@leicester.ac.uk	0116 258 5658
Local & National	Dermatology		<i>Dr Anton Alexandrov</i>	anton.alexandrov@uhl-tr.nhs.uk	0116 258 7562
Local & National	Ophthalmology		<i>Prof Irene Gottlob</i>	ig15@leicester.ac.uk	0116 258 5041
Local & National	Gastroenterology		<i>Prof Janusz Jankowski</i>	janusz.jankowski@uhl-tr.nhs.uk	0116 204 7864
Local	Infectious Diseases & Microbiology		<i>Dr Adrian Palfreeman</i>	adrian.palfreeman@uhl-tr.nhs.uk	0116 258 5859
Local & National	Injuries & Emergencies		<i>Prof Tim Coates</i>	tc61@leicester.ac.uk	0116 252 3263
Local & National	Paediatrics (non-medicines)		<i>Dr Monica Lakhanpaul</i>	ml103@leicester.ac.uk	
Local & National	Renal		<i>Prof Nigel Brunskill</i>	nigel.brunskill@uhl-tr.nhs.uk	0116 258 8043
Local & National	Urogenital & Urogynaecology		<i>Mr Masood Khan</i>	masood.khan@uhl-tr.nhs.uk	0116 258 4449
Local & National	Reproductive Health & Childbirth		<i>Mr Marwan Habiba</i>	mah6@leicester.ac.uk	0116 258 3170
	Respiratory		TBA		

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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
Respiratory	Refurbishment to provide additional clinical trial / research facilities	£300k	Autumn 2011
Diabetes	Refurbishment of two existing ward areas for a Diabetes Centre of Excellence	£600k	Summer 2011
Oncology	Refurbishment of existing an existing theatre area to provide further clinical research capacity	£350k	Autumn 2011
Cardiovascular Research Centre	University of Leicester are building and equipping a new four story research facility on the Glenfield Hospital Site	£12.6M	Spring 2012

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Organisation R&D Standard Operating Procedures Register

Standard Operating Procedures				
SOP Ref Number	SOP Title	SOP Details	Issue Date / Amendment Date	Review Date
UHL SOP CLIN/101	Preparation, Approval, Distribution, Amendment and Storage of Standard Operating Procedures		March 2006 Superseded September 2010	31/03/2012
UHL SOP CLIN/102	Informed Consent to include process of assessment for Non Medic, AHP & Nurses		March 2006 Superseded January 2010	31/03/2011
UHL SOP CLIN/104	Clinical Trials Authorisation		March 2006 Superseded March 2009	31/03/2011
UHL SOP CLIN/105	Study Specific R&D Files		March 2006 Superseded March 2009	31/03/2011
UHL SOP CLIN/106	Preparation of Clinical Trial Protocols and Procedures for Amendments		March 2006 Superseded March 2009	31/03/2011
UHL SOP CLIN/107	Protocol Amendments		March 2006 Superseded March 2009	31/03/2011
UHL SOP CLIN/108	Site Management (Monitoring) for Trust as Sponsor		March 2006	31/03/2011
UHL SOP CLIN/109	Processing and Reporting of Serious Adverse Events/Serious Adverse Reactions and Suspected Unexpected Serious Adverse Reactions		March 2006 Superseded 30/11/2010	31/03/2011
UHL SOP CLIN/110	Inspection by Regulatory Agencies		March 2006 Superseded March 2009	31/03/2011
UHL SOP CLIN/112	The review of Clinical Trials involving Pharmacy		March 2006	31/03/2011
UHL SOP CLIN/113	Sourcing a Supplier of a Placebo for In-House studies		March 2006	31/03/2011
UHL SOP CLIN/114	Research Agreements		March 2006 Superseded March 2009	31/03/2011
UHL SOP CLIN/115	Clinical Trials Management for In-house Sponsored Trials		March 2006 Superseded March 2009	31/03/2011
UHL SOP CLIN/116	Indemnity for Negligent/Non-negligent Harm		March 2006 Superseded March 2009	31/03/2011
UHL SOP CLIN/117	Suspected Fraud/Malpractice in Clinical Research		March 2006 Superseded January 2010	31/03/2011
UHL SOP CLIN/118	Laboratory Procedures		March 2006	31/03/2011
UHL SOP CLIN/119	Research Governance/ Sponsor Audit Policy		March 2006 Superseded March 2009	31/03/2011
UHL SOP CLIN/120	Data Protection Policy		March 2006 Superseded April 2009	31/03/2011
UHL SOP CLIN/121	Training in Staff Engaged in Clinical Trials		March 2006 Superseded January 2010	31/03/2011
UHL SOP CLIN/122	Equipment Maintenance/Calibration		March 2006	31/03/2011
UHL SOP CLIN/123	R&D Approval Process		March 2006 Superseded 18/09/2009	31/03/2011
UHL SOP CLIN/124	CI/PI Responsibilities		March 2006 Superseded March 2009	31/03/2011
UHL SOP CLIN/126	Tissue Bank Guidelines		March 2006 Superseded March 2009	31/03/2011
UHL SOP CLIN/127	Procedure in event of Non-Compliance		March 2009	31/03/2011
UHL SOP CLIN/128	Procedure for Transfer of Human Tissue		March 2009	31/03/2011
UHL SOP CLIN/129	Pre-approval of Studies involving Genetically Modified Materials and / or Gene Therapy		May 2009	31/03/2011
UHL SOP CLIN/130	Access to Patient Notes for Research		May 2006	31/03/2011
UHL SOP CLIN/131	Peer Review for studies under review for Sponsorship by University Hospitals of Leicester NHS Trust		November 2009	31/03/2011

UHL SOP CLIN/132	Risk Assessment of Clinical Trials of Medicinal Products and Device Trials		November 2009	31/03/2011
UHL SOP CLIN/133	Essential Study Documentation. Trial Master Files/Site Files		February 2010	31/03/2011
UHL SOP CLIN/134	Review of Research Proposals requiring University Hospitals of Leicester NHS Trust Sponsorship		February 2010	31/03/2011
UHL SOP CLIN/135	Self-Monitoring Procedures for Research Activity at University Hospitals of Leicester NHS Trust		March 2010	31/03/2011

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Information on the processes used for managing Research Passports

Indicate what processes are used for managing Research Passports

The process is as described in the Trust's Research Passport Policy (Trust ref B1/2010), approved by the Policy & Guideline Committee 18/01/10.

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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

Projects are processed by the RM&G Team in the Joint Trust and University R&D Office. Weekly project meetings provide a forum to flag any issues that may become a problem. Potential issues are escalated to the R&D Manager in the first instance, then to the Assistant Director, the Director and then to the R&D Committee for review. Where an expedited response is required, issues may be directly referred to the highest level within the Trust including the Chief Executive and within the University of Leicester to the Dean of the College of Medicine, Biological Sciences and Psychology.

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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

All research activity is entered onto the ReDA Research Management Database. We have access to CSP intelligence from the CLRN.

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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)

Information on research activity may be found on the Trust's website (www.uhl-tr.nhs.uk/ourservices/rd) and on the University of Leicester College of Medicine, Biological Sciences and Psychology website (www2.le.ac/colleges/medbiopsych/research).

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